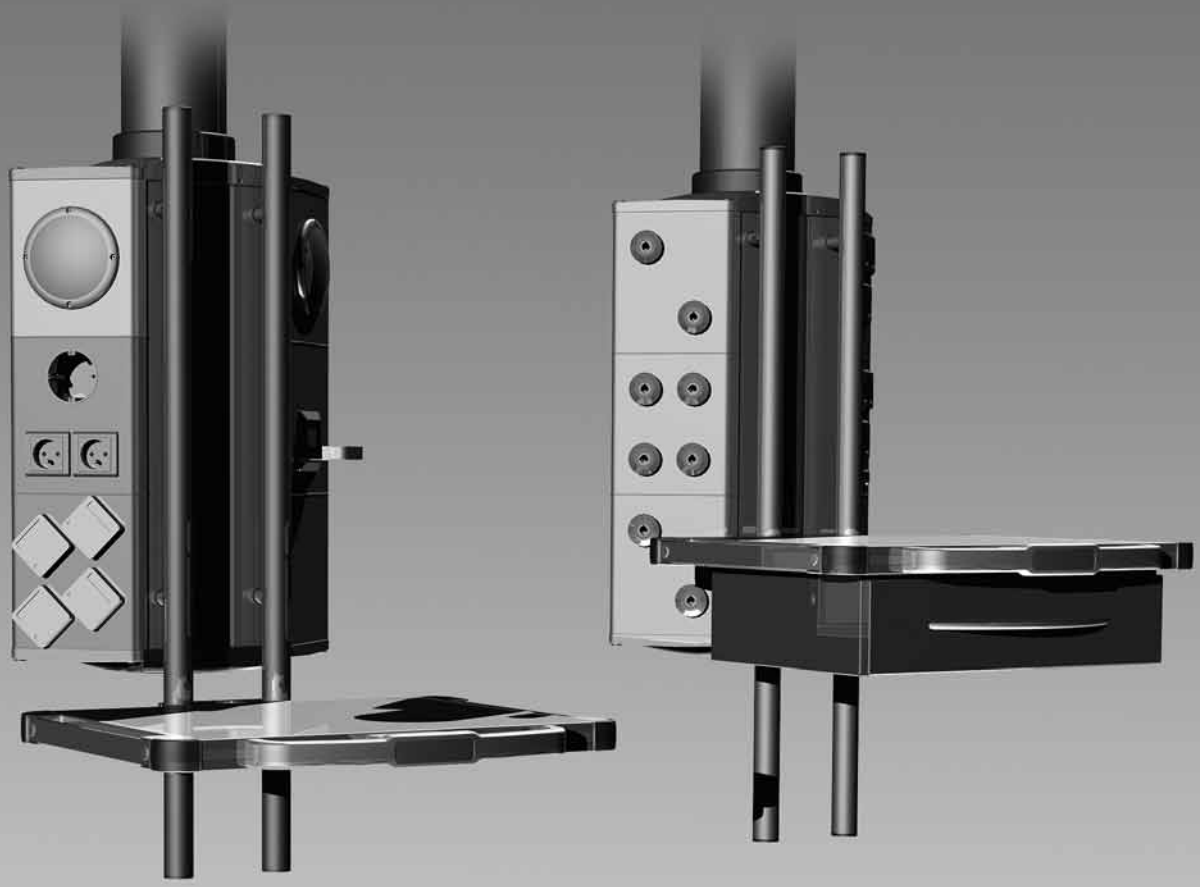

Installation Instructions Part 3 [EN]

Navigator M6

A member of the
Medical Illumination International Group

Dear assembly operator,

please read these Installation Instructions very carefully, and in particular Chapter 2, “Safety Instructions“ which includes important safety information. Observe the safety instructions and requirements set out in these Installation Instructions.

Service technician qualification requirements

- These Installation Instructions are intended for trained service technicians.
- The Nuvo pendant systems may only be installed by Nuvo service technicians or authorised service personnel trained by Nuvo.

Inspections to be performed prior to installation

- The load bearing capacity of the ceiling must be checked by a structural analyst and confirmed by means of an acceptance certificate.
- The electrical installations in the corresponding room must comply with the requirements of the applicable national and international regulations.

Carrying out the installation

- The electrical connection of the appliance to the mains may only be performed by a qualified electrician whilst the appliance is disconnected at all poles.
- The steps described in these Installation Instructions must be followed for installation. In the event of damage to the appliance, installation work must be discontinued.
- The safety, reliability and performance of the appliance are only assured if genuine parts from Nuvo are used.
- If you encounter specific problems not covered in sufficient detail by these Installation Instructions, please contact your supplier immediately for your own safety and the safety of your customers.

Unauthorised modifications or conversions

- Unauthorised modifications or conversions to the appliance are not permitted for safety reasons. No modification or conversion may be performed without authorization. Otherwise, the manufacturer's warranty for the appliance will be void. The manufacturer hereby rejects any liability whatsoever for damage or injury resulting from unauthorised modifications or conversions or from using spare parts from other manufacturers.
- The use of parts which were not supplied by the manufacturer or its representatives will automatically cause the warranty to become void.
  USE GENUINE SPARE PARTS ONLY!

Qualified personnel

The following persons shall be considered as qualified personnel:

- Persons who underwent special professional training in the field of medical engineering,
- persons who can assess their work and recognize the potential hazards involved on the basis of their professional experience and instruction in safety-relevant regulations.
- In States where the performance of tasks in the medical engineering sector is subject to certification, qualified personnel must have obtained the corresponding certificate.

How to contact us

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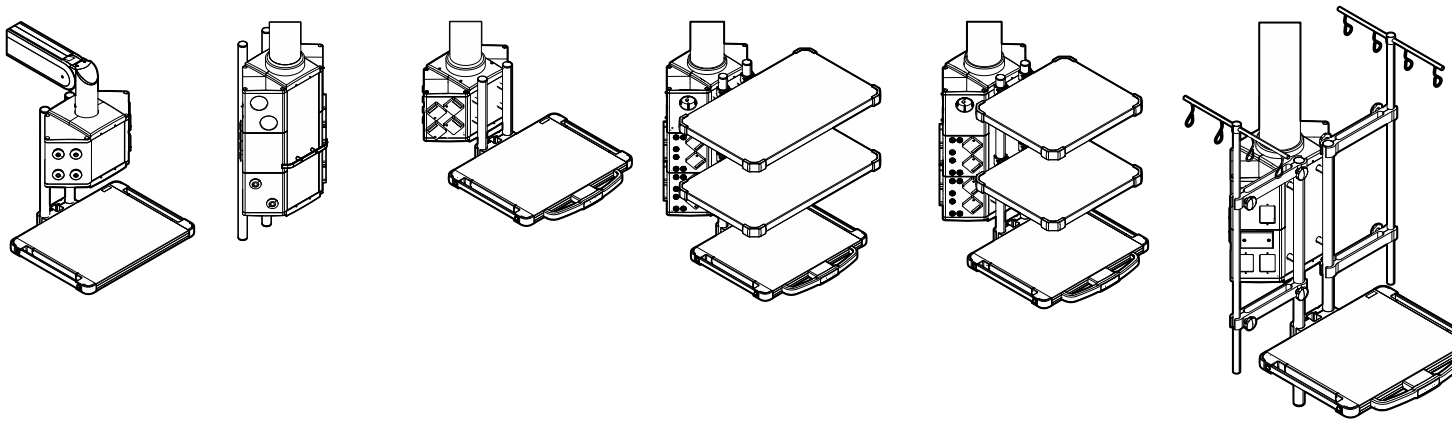
1568916, Edition 2019-05, Version 0

Visit us on the Internet www.nuvosurgical.com
E-mail address sales@nuvosurgical.com

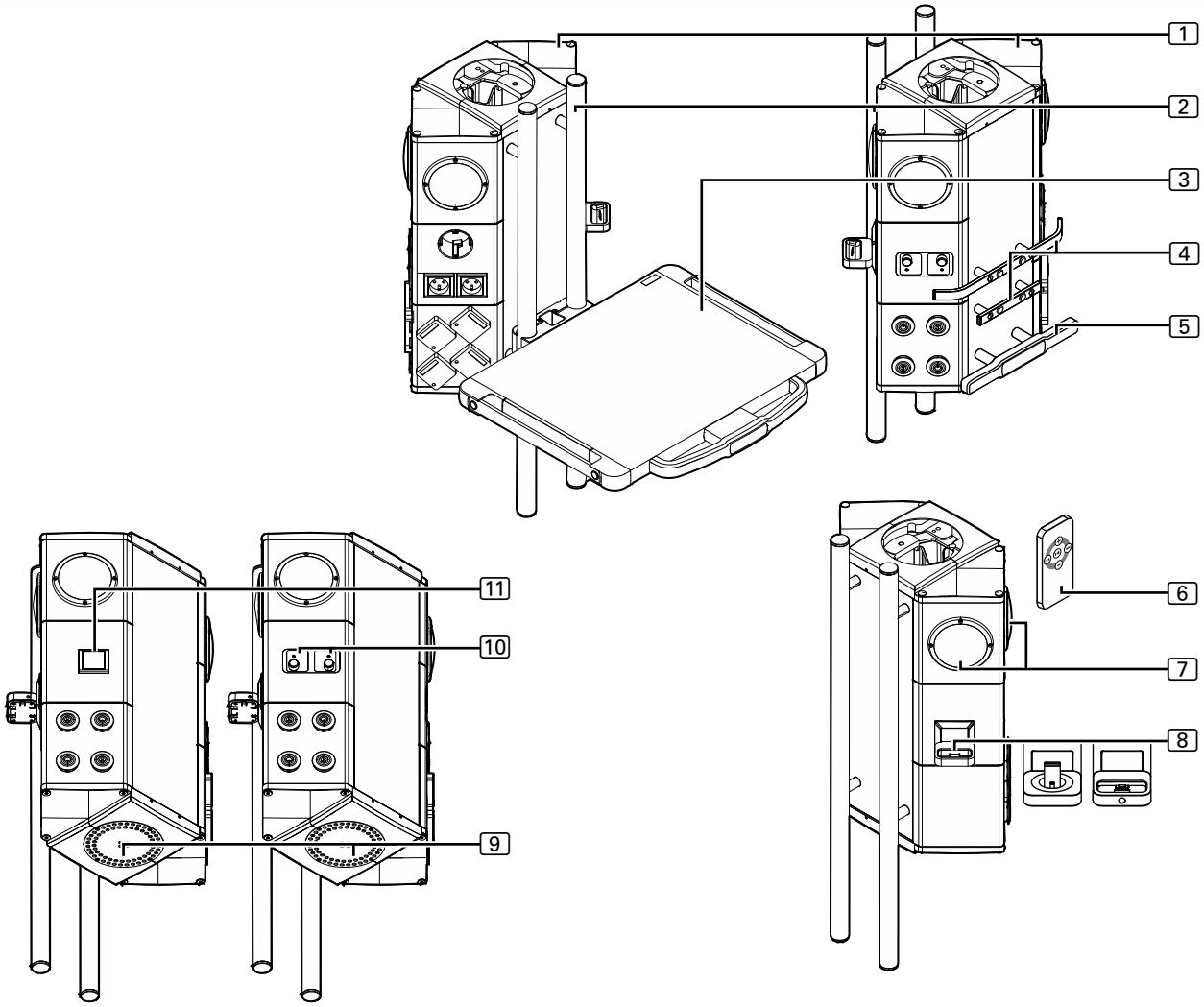
Configuration examples

The Navigator M6 in various equipment versions is combined with different Nuvo pendant systems depending on the medical discipline and individual space requirements.

SpacePort®	Navigator ™ / OndaScope® 400 / OndaScope® 600	Navigator Lift ™ 150 / Navigator Lift ™ 180 / MMP 85 S / MMP 90	Navigator Lift ™ 250 / MMP 200	Navigator ™ / OndaScope® 400 / OndaScope® 600	Navigator ™ / OndaScope® 400 / OndaScope® 600



Parts and control elements



The Figure shows examples for the configuration of the Navigator M6 for various medical disciplines on the approved Nuvo pendant system. The scope of delivery can vary depending on the individual order.

Installation as described in Chapter 6 on Page 20

[1] Navigator M6 (Standard or XL size)
- Navigator M6 (length as specified in the order) with:
- D-SUB plug connector for connecting the operating shelf for controlling a pendant system equipped with electromagnetic brakes
- Fitting aperture for the pneumatic compressed air lines for controlling a pendant system with pneumatic brakes
- 1 UP/DOWN button for the motor-powered height adjustment of the pendant systems MMP 90 / MMP 200

Pre-assembled component

[2] Optional Multi-Function Rack (MFR)
- 1 Multi-Function Rack (length as specified in the order)

Installation as described in Chapter 8 on Page 26

[3] Optional operating shelf
- 2 control buttons for operating the electromagnetic brakes on the pendant systems Navigator ™ / Navigator Lift ™ or the pneumatic brakes on the pendant systems Navigator ™ / Navigator Lift ™ and OndaScope® 400 / OndaScope® 600
- 1 UP/DOWN button for the motor-powered height adjustment of the pendant systems Navigator Lift ™ 150 / Navigator Lift ™ 250
- D-SUB plug connector on the rear of the operating shelf
- 3 pneumatic connectors at the bottom of the operating shelf

Fixing elements
- 1 holding clamp
- 2 Allen cylinder screws M8 x 50 mm – 8.8 – DIN 912
- 2 protective caps

Pre-assembled components

[4] Standard rail (optional – Straight or Bent versions) with:
- 2 optional control buttons for operating the pneumatic brakes on the pendant system OndaScope® 400 / OndaScope® 600 and the Multi-Movement Pendant MMP 90 / MMP 200

Pre-assembled components

[5] Optional operator handle with:
- 2 control buttons for operating the electromagnetic brakes on the pendant systems Navigator ™ / Navigator Lift ™
- 1 UP/DOWN button for the motor-powered height adjustment of the pendant systems Navigator Lift ™ 150 / Navigator Lift ™ 250

Optional sound system

Installation as described in Chapter 9 on Page 28

[6] Remote control unit for the version MediSound-System Interface

[7] 4 loudspeakers
- in the Navigator M6 or
- 1 spherical loudspeaker (optional), ceiling-mounted (not illustrated)

[8] Docking station for external digital media players
such as MP3 players, smartphones, Apple iPhones or Apple iPods (not included in the scope of delivery)
- Version MediSound-System Bluetooth with 3 interfaces or
- MediSound-System Interface with 2 interfaces, control buttons at the bottom and battery charging function

Optional lighting systems (only pendant systems Navigator ™ and Navigator Lift ™)

Pre-assembled components

[9] Indirect Navigator M6 lighting (SurroundLED basic F)
- with air vents (must not be covered)

[10] 2 rotary dimmer switches with luminous display with indicator lamps for
- controlling the indirect extension arm lighting and the indirect Navigator M6 lighting (SurroundLED advanced)

[11] ON/OFF switch for
- the indirect extension arm lighting (SurroundLED basic C, not illustrated) or the indirect Navigator M6 lighting (SurroundLED basic F)

2.1 Approved Nuvo products

Approved Nuvo products

The following Nuvo products are approved for installation on the Navigator M6:

- Chapter 16, “Approved Nuvo Products”, on Page 43,
- Chapter 17, “Approved Third-Party Products”, on Page 43.

2.2 Combination with products of other manufacturers

Read the Installation Instructions for combined products

- The Navigator M6 is combined with Nuvo accessories as described in Chapter 16, “Approved Nuvo Products”, on Page 43 and with third-party products as described in Chapter 17, “Approved Third-Party Products”, on Page 43.
  To prevent dangerous overload, which can damage or lead to a collapse of the pendant system and the Navigator M6, the maximum loading capacities specified must be adhered to:
  – The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.
  – Read the Installation Instructions provided by the third-party manufacturer and in particular the relevant pages with information on the installation of the end device.
- Power packs intended for the supply of end devices must ensure electrical isolation and provide two protective measures in accordance with IEC 60601-1.

2.3 Structure of the safety instructions

2.3.1 Warnings of risk of injury

Important notes in this document are marked with graphic symbols and signal words. Signal words such as DANGER, WARNING or CAUTION describe the degree of risk of injury. The triangle symbols visually emphasise the degree of hazard.

⚠ DANGER

DANGER refers to a potential hazard with a high degree of risk which, if not avoided, will lead to death or severe injury.

⚠ WARNING

WARNING refers to a potential hazard with a medium degree of risk which, if not avoided, can lead to death or severe injury.

⚠ CAUTION

CAUTION refers to a potential hazard with a low degree of risk which, if not avoided, can lead to minor or moderate injury.

2.3.2 Warnings of damage to property

NOTICE

NOTICE refers to a potential hazard, which, if not avoided, will lead to damage to property.

2.3.3 Indication of additional information

NOTE

A NOTE provides additional information and useful tips for the safe and efficient use of the device.

2.4 Supplementary symbols used in the safety instructions

Explosion hazard: warns of the improper use of oxygen (see Chapter 2.8.2 on Page 13).

Danger of fire: warns of the improper use of oxygen (see Chapter 2.8.2 on Page 13).

Electric shock hazard: warns of electric shock which can lead to severe injury or even death.

Risk of the Navigator M6 dropping: warns of the risk of the Navigator M6 suddenly dropping because the maximum loading capacity has been exceeded.

Risk of parts falling off: warns of parts falling off while carrying out installation or dismantling work underneath the pendant system.

Tightening torque: warns of the Navigator M6 dropping because the fixing screws have not been sufficiently tightened or not tightened at all.

Battery disposal: Batteries contain toxic substances. Never dispose of batteries as normal household waste; return them to the collection points provided by shops or dispose of them at waste management facilities under public law. For transport or disposal, cover the battery connectors with insulating tape in order to prevent accidental short circuits.

2.5 Graphic symbols on the device and/or on the packaging

Read the Installation Instructions: Read these Installation Instructions carefully prior to installation of the Navigator M6. This ensures that you benefit from all the advantages of the Navigator M6 and prevents any risk of injury or material damage.

Observe the maximum load bearing capacity or maximum loading capacity (payload): warns of the risk of the Navigator M6 suddenly dropping because the maximum load bearing capacity or maximum loading capacity (payload) has been exceeded. The maximum value is indicated in kg or Nm.

General note reminding the user to handle the Navigator M6 with care.

Environmentally friendly disposal: warns of damage to the environment caused by improper disposal of the Navigator M6 (must not be disposed of as normal household waste).

ESD component: warns of a high current pulse caused e.g. through frictional electricity which, when coming into contact with the docking station, triggers an electrostatic discharge that can damage microelectrical components.

Non-ionising electromagnetic radiation: warns that the high-frequency electromagnetic radiation generated by base transceiver stations and radio transmitters interferes with medical devices and electronic implants.

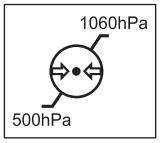
Equipotential bonding: marks the equipotential bonding connections to be used for earthing end devices (e.g. flat screens).

Do not loosen the screws: warns of the Navigator M6 suddenly dropping because the screws indicated have been loosened.

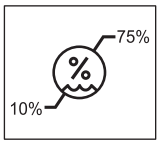
CE mark: Nuvo declares that the products comply with the relevant regulations set forth in the applicable European Directives.

CE mark with the ID number of the conformity assessment body indicated: Nuvo declares that the assessment of conformity in accordance with 93/42 EEC (Medical Device Directive) has been performed by the body indicated.

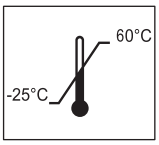
This symbol marks the product as a component approved by a "Nationally Recognized Testing Laboratory" which complies with both Canadian and US deviations from applicable standards.



Atmospheric pressure: indicates the permissible atmospheric pressure values in a range from 500 hPa to 1060 hPa for transport and storage.



Relative humidity: indicates the permissible humidity values in a range from 10 % to 75 % for transport and storage.



Ambient temperature: indicates the permissible ambient temperature values in a range from -25 °C to 60 °C for transport and storage.

2.6 Intended purpose

- The Navigator M6 on the Nuvo pendant system is individually equipped; depending on the version and equipment, it serves for:
– carrying and positioning medical devices in OR or intensive care rooms and medical environments;
- the conveying and extraction of fluids:
– medical gases, vacuum and compressed air,
– electricity and data.

- The Navigator M6 is suitable for continuous operation.

Qualified personnel

- The Navigator M6 may only be operated by instructed, qualified medical personnel.
- The Navigator M6 may only be cleaned and disinfected by instructed hygiene specialists.
- Maintenance work on the Navigator M6 must be carried out by the operator's technical specialist personnel in accordance with the applicable instruction document.

2.6.1 Incorrect use

- The maximum loading capacity of the Navigator M6 and its components as specified in Chapter 14, “Technical Data”, on Page 35 must not be exceeded.
- Independently of the maximum loading capacity (payload) the optional components may only be loaded with the maximum weight specified in Chapter 16, “Approved Nuvo Products”, on Page 43.

Duty cycle of the height adjustment mechanism (only pendant systems MMP 90 / MMP 200 and Navigator Lift ™ 150 / Navigator Lift ™ 250)

- The maximum duty cycle of the height adjustment mechanism on the motor arm (only pendant systems MMP 90 / MMP 200 and Navigator Lift ™ 150 / Navigator Lift ™ 250) must not exceed 3 minutes:
– If the height adjustment mechanism is actuated over a longer period of time, the electric motor of the motor arm may switch off automatically as a protection measure against overheating.
– In order to prevent an overload of the electric motor, make sure you wait at least 30 minutes after actuating the height adjustment mechanism before putting the height adjustment mechanism into operation. Afterwards the height adjustment mechanism can be operated once again for 3 minutes.

Duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes)

- The maximum duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes) must not exceed 1 minute:
– If the electromagnetic brakes are actuated over a longer period of time, the power pack may switch off automatically as a protection measure against overheating.
– Once the power pack has switched off, it must cool down for 10 minutes and then be disconnected from the mains for 10 seconds before being switched back on again. Normal system operation may only be resumed afterwards. To prevent safety cut-offs, the maximum duty cycle should not be exceeded.

2.6.2 Contraindications

- The Navigator M6 must not be used close to strong magnetic fields.
- No BF or CF application parts in accordance with IEC 60601-1 may be directly connected to the Navigator M6.

2.7 Ambient conditions

2.7.1 Ambient conditions for storage and transport

The following conditions apply to storage:

- Ambient temperature: -25 °C to 60 °C
- Relative humidity: 10 % to 75 %
- Atmospheric pressure: 500 hPa to 1,060 hPa
  Store only in indoor rooms.

2.7.2 Ambient conditions for operation

- Ambient temperature: 10 °C to 40 °C
- Relative humidity: 30 % to 75 %
  Atmospheric pressure: 700 hPa to 1,060 hPa
  (This corresponds to a maximum operating altitude of 3,000 m).

2.8 Overview of the most important safety instructions

The safety instructions in the following chapters must be adhered to.

2.8.1 Mounting

⚠ DANGER

The pendant system and the Navigator M6 can drop if the maximum loading capacity (payload) is exceeded

If the maximum permissible loading capacity (maximum payload) has been exceeded, there is a risk that the pendant system, the Navigator M6 or components of the pendant system may disengage from the fastening device and drop:

- The total weight of the fixedly attached or placed end devices, accessories, etc. must not exceed the maximum permissible loading capacity (payload) indicated on the Navigator M6.
- Independently of the maximum loading capacity (payload) on the Navigator M6, optional accessories may only be loaded with the maximum weight specified in Chapter 16, “Approved Nuvo Products”, on Page 43.

If you cannot clearly determine the maximum loading capacity (payload), contact Nuvo in order to prevent damage to persons or property.

- Phone: +1 (800) 663-1152 (USA and CANADA)
- Phone: +1 (814) 899-4220 (INTERNATIONAL)

⚠WARNING

Electric shock hazard

To prevent the risk of electric shock, the pendant system and the Navigator M6 may only be connected to a supply network equipped with a protective conductor:

- The pendant system and the Navigator M6 must be connected in such a way that they can be disconnected from the mains at all poles and at the same time.

Electric shock hazard

Power cables are laid in the pendant system and the Navigator M6. Contact with energized components presents a danger to life from electric shock. Prior to any installation/dismantling and setting up work, the pendant system and the Navigator M6 must be disconnected from the mains:

- Disconnect all the poles from the mains and prevent the device from being switched back on again.
- Make sure that all the devices connected via the Navigator M6 are de-energised.

⚠WARNING

Risk of parts falling off

During all uninstallation / installation work, it must be ensured that no person is in the area underneath the components of the pendant system.

Risk of the Navigator M6 dropping

If the fastening screws marked are loosened, the Navigator M6 will drop:

- Do not loosen the screws indicated.

The tightening torques are marked in these Installation Instructions:

- Observe the tightening torques indicated in these Installation Instructions.

2.8.2 Proper use of oxygen

⚠ DANGER

Oxygen explosion

Oxygen becomes explosive when in contact with oil, grease and lubricants. Compressed oxygen presents an explosion hazard:

- Make sure that the oxygen and gas outlet points are free from oily, greasy and lubricating materials!
- Do not use any cleaning agents containing oil, grease or lubricants.

Danger of fire

Escaping oxygen is combustible:

- Open fires, red hot objects and naked flames are not permitted when working with oxygen!
- Do not smoke!

2.8.3 Ventilation at the bottom of the Navigator M6

⚠ DANGER

Danger of fire

Escaping oxygen is combustible: If the air vents [9] at the bottom of the Navigator M6 are covered, there is a risk of oxygen enrichment in the Navigator M6 in case of failure of optional oxygen hoses:

- Make sure the air inlets are not covered.
- Attachments to the bottom of the Navigator M6 must be installed at a minimum distance of 50 mm from the air inlets.

2.9 Warranty

⚠ WARNING

Pendant system dropping

The pendant system and the Navigator M6 are an adapted system with regard to their maximum load bearing capacity and maximum loading capacity (payload).
Alterations to the pendant system can result in exceeding the permissible, total or maximum loading capacity (system load) of individual components. In this case, there is a risk of the pendant system or components thereof disengaging from the fastening device and dropping.
Nuvo warrants the functional reliability of the pendant system only under the condition that:

- No structural alterations are made to the pendant system. Unauthorised modifications or conversions to the pendant system are not permitted for safety reasons.
- Only genuine spare parts or accessories and those defined and approved by Nuvo are used. The use of other parts may involve unknown risks and must be avoided in all cases.
- Inspections and maintenance are carried out at the specified time intervals.
- Related documents for dismantling, mounting and adjustment work to be carried out on the pendant system are available from Nuvo on request.
- The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required, and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.

2.10 Electromagnetic interference

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the instructions below.
The instructions in Chapter 15, “Electromagnetic Compatibility (EMC) Information”, on Page 38 must also be observed.

⚠WARNING

Failure of medical devices

Portable and mobile high-frequency communication devices (e.g. MP3 players, Apple iPods and iPhones) can interfere with medical electrical devices or their displays and put essential patient supply measures at risk:

- Do not operate MP3 players, Apple iPods and iPhones immediately next to or together with medical electrical devices.
- If the devices mentioned above must be operated next to or together with medical electrical devices, the medical electrical device should be observed in order to ensure its proper operation.

Do not use third-party accessories

The use of other accessories, including converters, adapters or cables, than those approved – except for the spare parts provided by the manufacturer for internal components – can result in increased emitted interference from the MP3 player, Apple iPod or iPhone. This interference can impact medical electrical devices and put important patient supply measures at risk:

- Use approved accessories (adapters, plugs, etc.) or accessories specified in Chapter 9, “Mounting the Sound System Components”, on Page 28 only.

Keep a distance from other electrical devices

The Navigator M6 can be influenced by the electromagnetic radiation of other electrical devices even if these comply with the emission requirements specified by the CISPR (International Special Committee on Radio Interference):

- Do not operate the Navigator M6 immediately next to or together with other electrical devices.
- If operation next to or together with other electrical devices is required, the Navigator M6 should be observed in order to ensure its proper operation.

2.11 Electromagnetic discharge

NOTICE

Do not touch plugs

Do not touch the pins of plugs marked with the ESD symbol with your fingers or handheld tools. Electrostatic discharge can cause the operator to suffer an electric shock or damage or even destroy microelectrical components.

Take the following protection measures:

- Do not touch the pins of the plugs in the docking station with your fingers or handheld tools.
- To earth your body, touch the Multi-Function Rack (MFR) or a metal part of the Navigator M6 once.
- Minimise the electrostatic discharge hazard through preventive measures (e.g. air conditioning, air humidification, conductive floor covering or non-synthetic clothes).

Train personnel

The operator should train all staff members exposed to the hazards mentioned above:

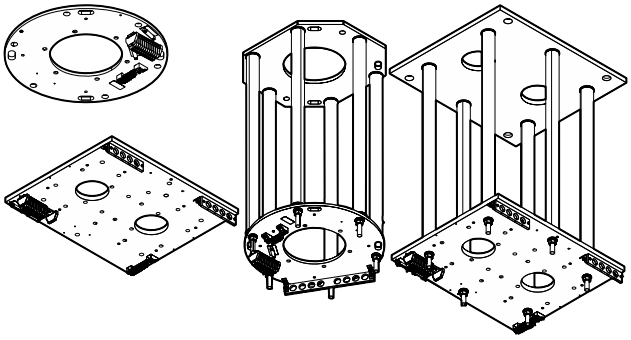
- Explain the ESD symbol;
- explain potential electrostatic discharges and the potential destruction of microelectrical components by touching electrostatically charged operators;
- explain the necessity of discharging one's own body prior to touching medical electrical devices;
- explain and train ESD protective measures to avoid electrostatic discharge.

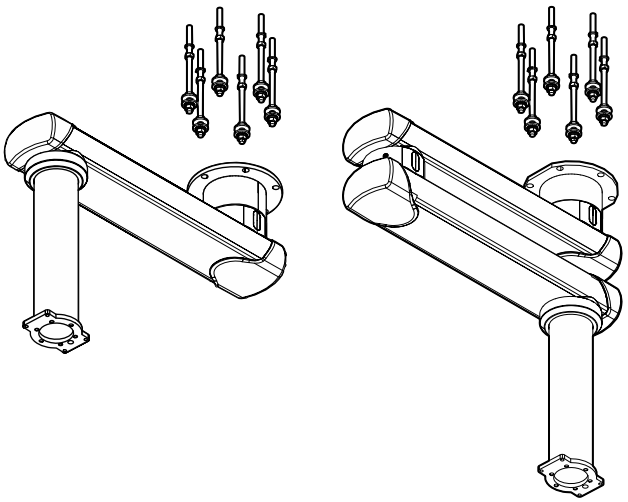
2.12 Disposal

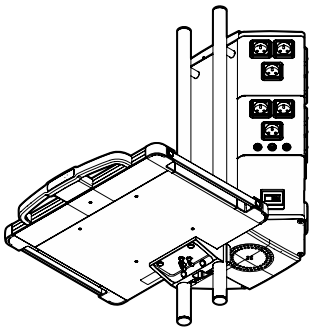
RoHS conformity

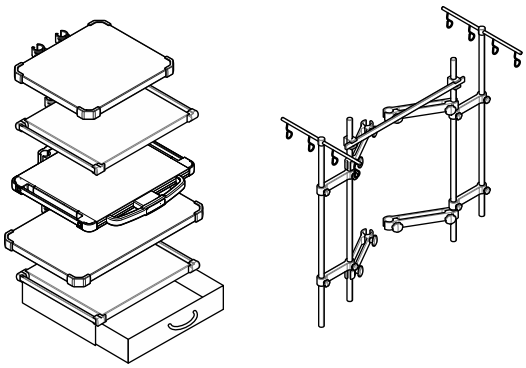
- The pendant system and the Navigator M6 comply with the requirements of the 2011/65/EC RoHS Directive (on the restricted use of certain hazardous substances in electrical and electronic equipment).
- To prevent environmental damage and personal injury, we therefore request you to contact us or your authorised service partner if you intend to take the pendant system and the Navigator M6 definitively out of operation for the purpose of disposal.
- The pendant system and the Navigator M6 must be disposed of at a suitable collection point for recyclable waste in accordance with country-specific regulations.

Figure 1: Overview of the structure of these Installation Instructions









The Installation Instructions for the entire pendant system consist of separate documents. For this reason, these Installation Instructions are only valid and complete if all the documents are available at the place of installation.
The following parts must be available:

Part 01: Ceiling mount
Interface plate on the raw ceiling
Intermediate ceiling set and interface plate

Part 02: Pendant system (example of Navigator ™)

Part 03: Navigator M6

Part 04: Accessories approved for the Navigator M6

- Lifting device or forklift with a permitted payload of at least 250 kg
  Alternatively, a hoisting winch with a permissible payload of at least 250 kg can be used if space is limited:
  – Check that the pendant system is sufficiently secured before lifting it.
  – When lifting the pendant system, make sure you avoid collisions with other pendant systems, devices, ceilings or walls and other assemblies.

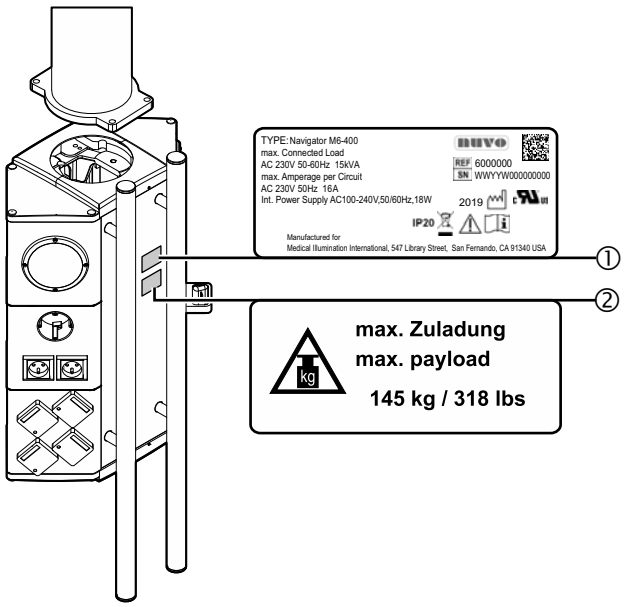
- Protective gloves

- Digital spirit level
- Torque wrench
- Multimetre
- Standard tool kit

- Working platform (e.g. pedestal ladder) in accordance with country-specific occupational health and safety regulations

5 Rating Plate and Labels

Figure 2: Checking the assignment to the pendant system using the labels



5.1 Checking the assignment to the pendant system using the labels

(See "Figure 2")

With regard to its maximum loading capacity (payload), the Navigator M6 has been designed and approved for a specific Nuvo pendant system.

⚠WARNING

Pendant system dropping

If the Navigator M6 is installed to a different pendant system, there is a risk that the pendant system may drop:

- Install the Navigator M6 to the specific pendant system for which it is intended as described in the Installation Instructions included in the scope of delivery.
- The Navigator M6 must not be mounted onto any other pendant system.

1. The Navigator M6 is provided with a label ② under the rating plate ①:
   – The label ② indicates the maximum loading capacity (payload) approved for the specific Nuvo pendant system (see Chapter 5.2 on Page 19).
2. Check that the Navigator M6 is assigned to the appropriate Nuvo pendant system.

Figure 3: Label indicating the maximum loading capacity (payload)

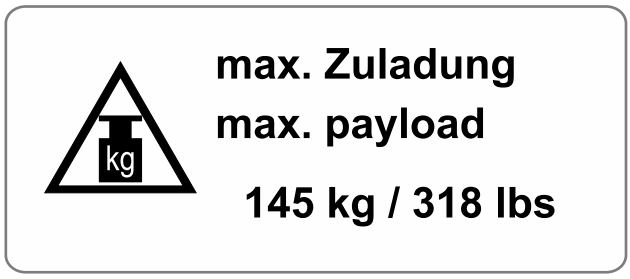
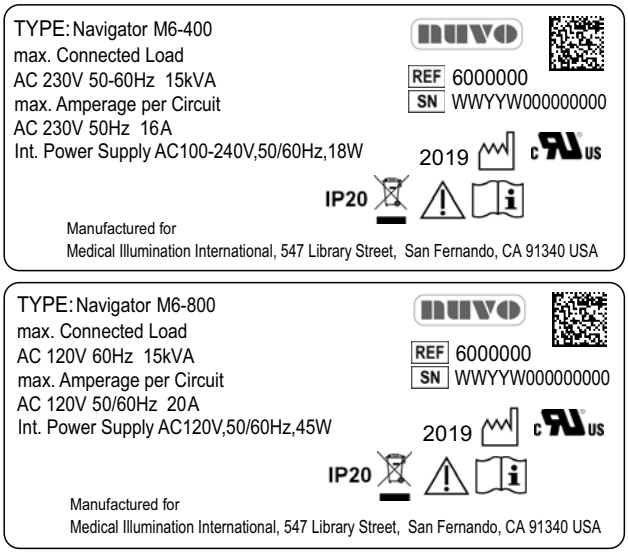


Figure 4: Rating plate with serial number and indication of the supply voltage



5.2 Label indicating the maximum loading capacity (payload) of the Navigator M6

(See "Figure 3")

- The label shows the example of the Navigator M6 with a maximum loading capacity (payload) of 145 kg / 318 lbs
- If a Multi-Function Rack (MFR), an operator handle or a standard rail is mounted onto the Navigator M6, the dead weight of these components is already included.
  If accessories such as an operating shelf are mounted onto the Multi-Function Rack (MFR), the dead weight must be subtracted from the maximum loading capacity (payload), see Chapter 7.3, “Checking the maximum loading capacity (payload)”, on Page 25.
- The information and illustrations serve as examples.

5.3 Information on the rating plate

(See "Figure 4")

The rating plate is attached:

- to the front side of the Navigator M6.

Serial number

- The rating plate indicates the serial number (SN) of the Navigator M6.

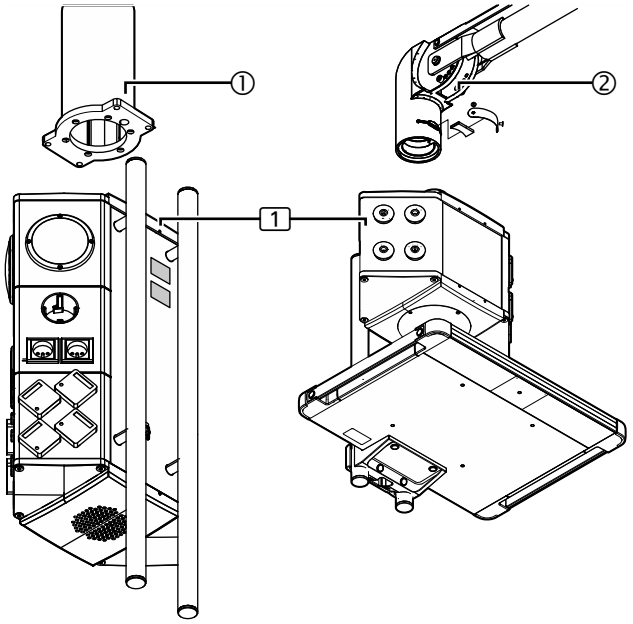
Power supply

- The rating plate provides information on the power supply of the Navigator M6.

Date of manufacture

- The digits 1 to 4 of the serial number (SN) indicate the date of manufacture.
  - The first two digits indicate the week of manufacture, e.g. 15 = calendar week 15.
  - The following two digits indicate the year of manufacture, e.g. 14 = 2014.
  - The letter in the 5th position indicates the factory, e.g. H = Hünfeld.
  - The digits following the letter indicate the serial number.
- The information and illustrations serve as examples.
- The information and illustrations on the rating plate can vary. Rating plates without a file number under the UL symbol are approved for IEC 60601-1, second and / or third edition.

Figure 5: Components described in this chapter



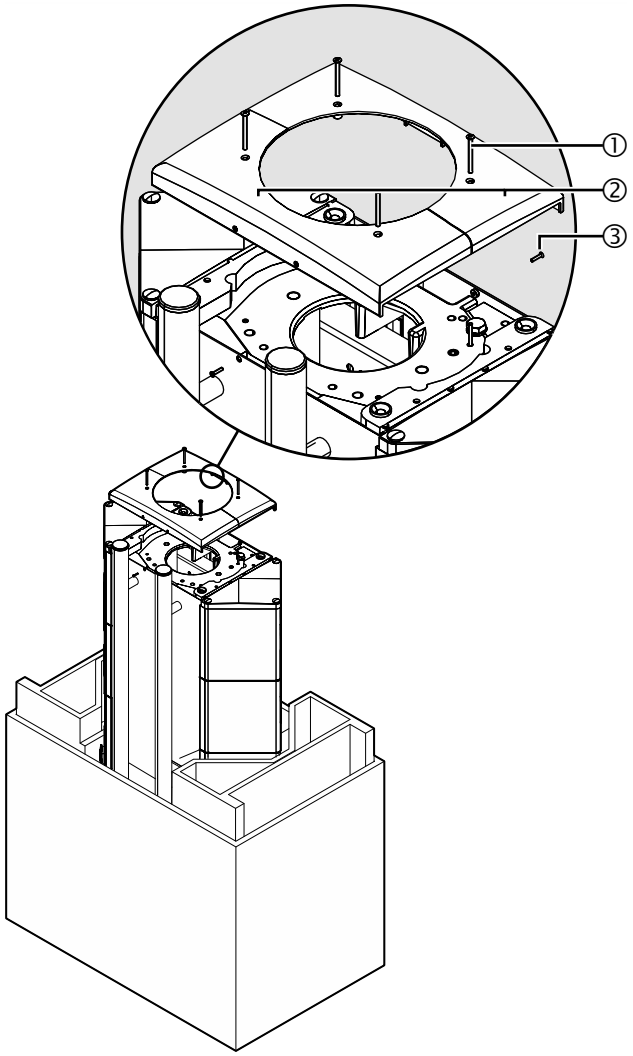
6.1 Components described in this chapter

(See "Figure 5")

The Figure shows a simplified illustration of the Navigator M6 [1] without pre-assembled cables.

- The Navigator M6 [1] is mounted onto the Drop tube ① or the SpacePort® spring arm ②:
  – The installation of the Navigator M6 onto the Drop tube ① is described in the following chapters.
  – For more detailed information on how to install the Navigator M6 onto the SpacePort® spring arm ② refer to the Nuvo Installation Instructions SpacePort® No. 1557993.
- For more detailed information on how to install the shelf refer to Chapter 8 on Page 26.

Figure 6: The package of the Navigator M6 serves as an installation aid.



6.2 Mounting the Navigator M6

6.2.1 Dismantling the top covers from the Navigator M6

(See "Figure 6")

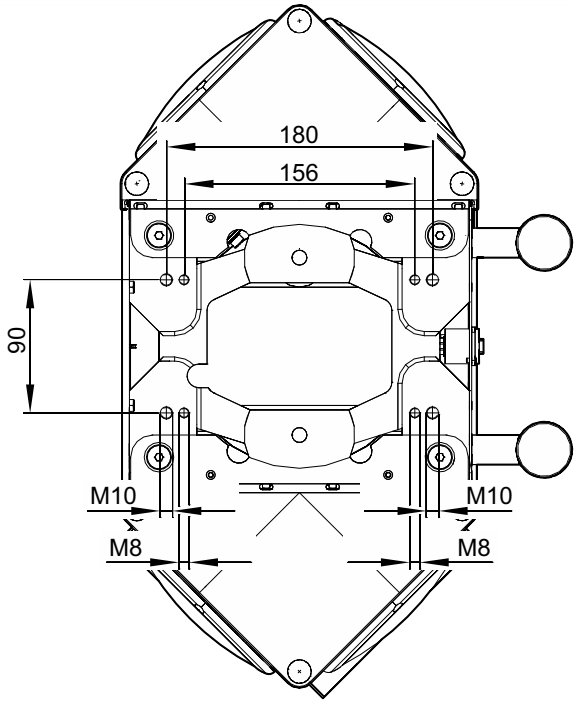
The Figure shows a simplified illustration of the Navigator M6 without pre-assembled cables.
The package of the Navigator M6 serves as an installation aid. Leave the Navigator M6 in the package as shown in the illustration.

1. Only for the Navigator M6, size XL:
   Unscrew 2 countersunk fillister head screws M4 x 40 mm ① – DIN 966 from each cover ②.

2. Unscrew 2 countersunk fillister head screws M3 x 12 mm ③ – DIN 966 from the front and rear sides.
3. Push the cover panels ② approx. 2 cm away from the Navigator M6 towards the outside and then remove the cover panels ② towards the top.

4. Keep the dismantled parts in a clean place.

Figure 7: Assignment of the threaded bolts to the pendant system



6.2.2 Assignment of the threaded bolts to the pendant system

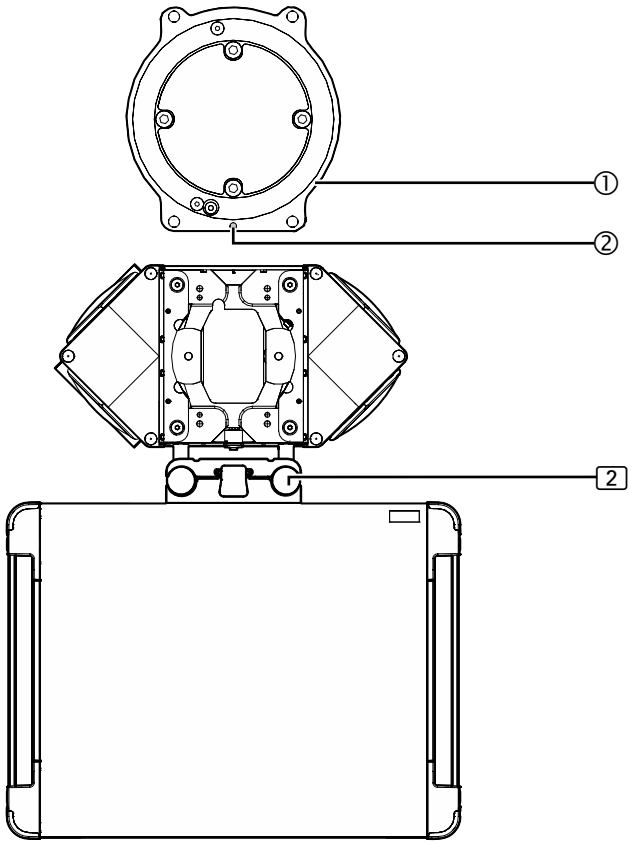
(See "Figure 7")

The Navigator M6 has 4 threaded bolts each with M8 and M10 thread diameters.

The M8 threaded bolts serve for installing the pendant systems:
- Navigator ™
- Multi-Movement Pendants MMP 85 and MMP 90
- Multi-Movement Pendant MMP 200
- Navigator Lift ™ 150
- Navigator Lift ™ 180

The M10 threaded bolts serve for installing the following pendant systems:
- OndaScope® 400
- OndaScope® 600
- Navigator ™ XL
- Navigator ™ XXL
- Navigator Lift ™ 250

Figure 8: Aligning the Navigator M6 during the installation to adjustable height pendant systems



6.2.3 Aligning the Navigator M6 during the installation to adjustable height pendant systems

(See "Figure 8")

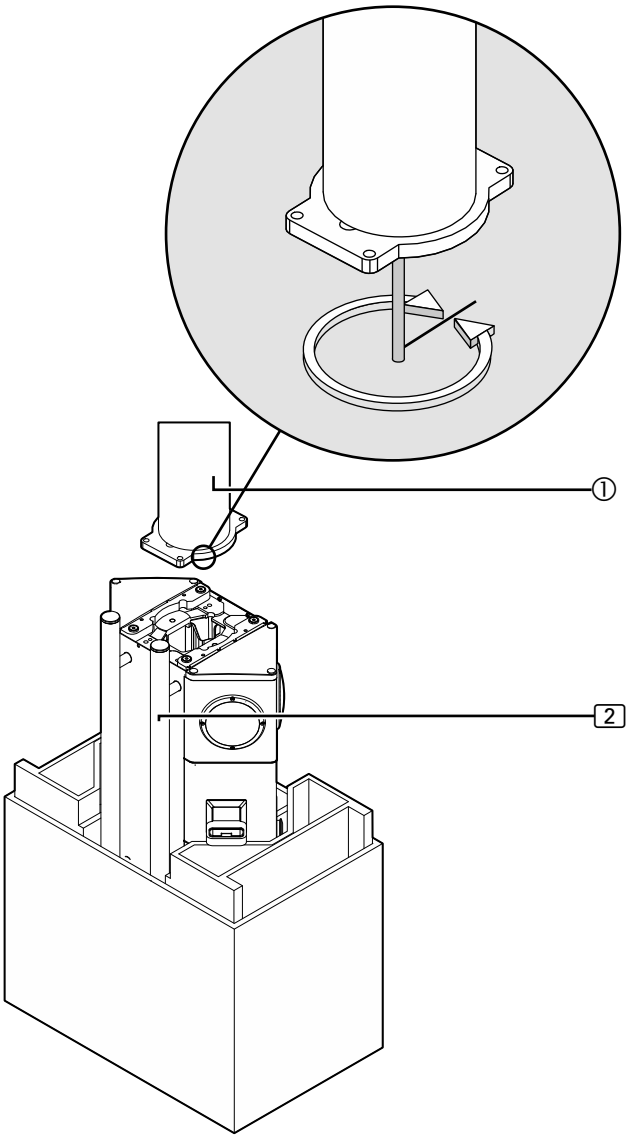
The Drop tube illustrated in the Figure has a specific geometry adapted to a special pendant system and may differ from the geometry of your Drop tube.

To avoid misalignment of the Navigator M6, the flange on the Drop tube ① is chamfered for adjustable height pendant systems.

For this reason, the Navigator M6 must be aligned when installing it to an adjustable height pendant system (types MMP 90 / MMP 200 and Navigator Lift ™ 180 / Navigator Lift ™ 250).

The mark ② (flat hole) at the bottom of the Drop tube ① serves for this purpose.
The Navigator M6 must be installed such that the Multi-Function Rack (MFR) [2] (or the more heavily loaded side of the Navigator M6) is on the side bearing this mark ② (flat hole).

Figure 9: Positioning the Navigator M6 under the Drop tube and routing the cables into the pendant system



6.2.4 Positioning the Navigator M6 under the Drop tube and routing the cables through the pendant system

(See "Figure 9")

The Figure shows a simplified illustration of the Navigator M6 without pre-assembled cables.
The Drop tube illustrated in the Figure has a specific geometry adapted to a special pendant system and may differ from the geometry of your Drop tube.

⚠WARNING

Risk of parts falling off

Make sure that no-one is standing underneath the components of the Navigator M6 whilst it is being installed.

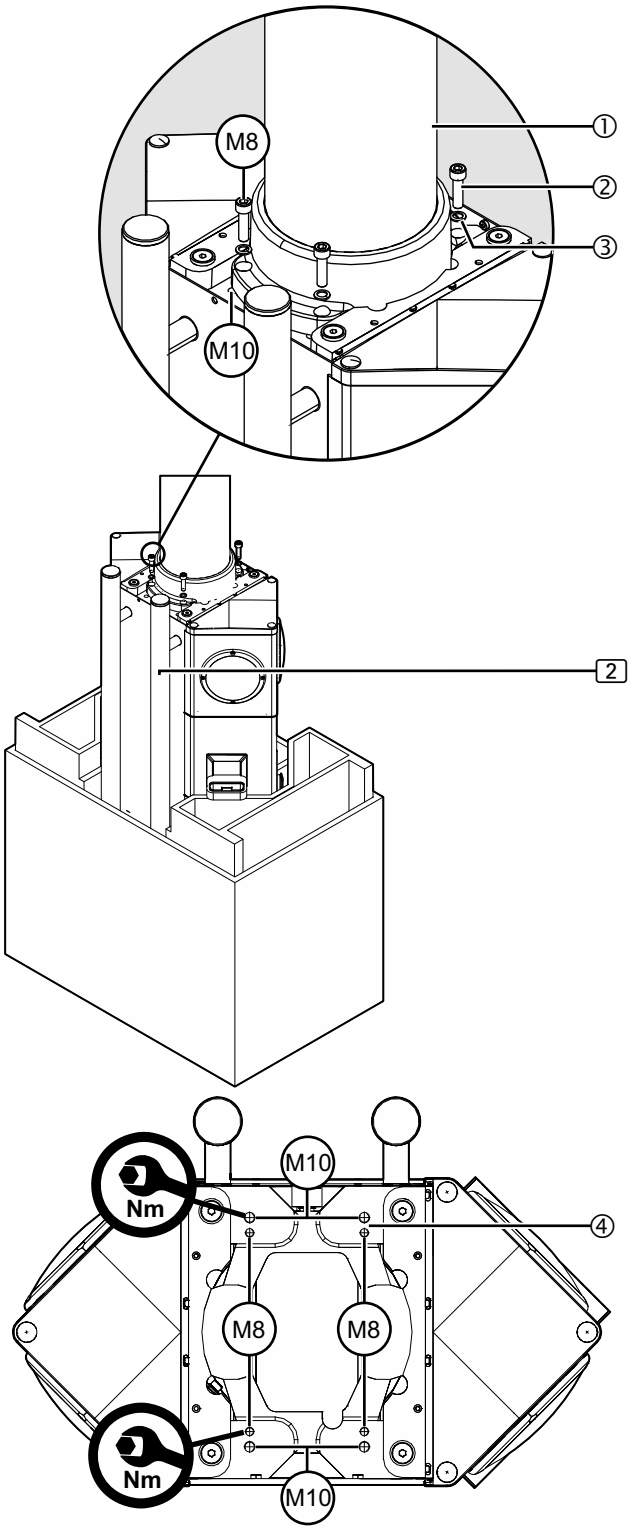
1. Securely attach the Navigator M6 to a suitable lifting device.
2. Turn the Drop tube ① in such a way that the end stop (rotational limit stop) is positioned under the extension, spring or motor arm.
- The end stop range of some pendant systems can be subsequently modified. For more detailed information, refer to the currently applicable Installation Instructions of the pendant system.
3. Position the Navigator M6 under the Drop tube ① such that the Multi-Function Rack (MFR) [2] on the Navigator M6 points away from the extension, spring or motor arm.

For more detailed information on how to route and connect the cables, refer to the currently applicable Installation Instructions of the pendant system:
- MMP 85 and MMP 90: No. 1527563
- MMP 200: No. 1510024
- Navigator Lift ™ 180: No. 1568909
- Navigator Lift ™ 180 Air: No. 1568908
- Navigator Lift ™ 250: No. 1568911
- Navigator Lift ™ 250 Air: No. 1568910

- OndaScope® 400: No. 1517827
- OndaScope® 600: No. 1510262
- Navigator ™ , Navigator ™ XL, Navigator ™ XXL: No. 1568907
- Navigator ™ Air, Navigator ™ Air<3_1_Kursiv>Plus: No. 1568883

Marking the pneumatic hoses (only for pendant systems with pneumatic brakes)
- Supply air (P) = Grey hose clip
- Brake 1 = Green hose clip for the upper extension arm
- Brake 2 = Blue hose clip for the lower extension arm, spring arm or motor arm
- Brake 3 = Blue hose clip for the Drop tube

Figure 10: Screwing the Navigator M6 onto the Drop tube



6.2.5 Screwing the Navigator M6 to the Drop tube

(See "Figure 10")

The Drop tube illustrated in the Figure has a specific geometry adapted to a special pendant system and may differ from the geometry of your Drop tube.

1. Align the Navigator M6 with the adjustable height pendant system as described in Chapter 6.2.3 on Page 21.
2. Assign the M8 or M10④ threaded bolts to the pendant system as described in Chapter 6.2.2 on Page 21.

3. Using 4 Allen cylinder screws M8 – 8.8 or M10 – 8.8② and 4 securing discs③, screw the Navigator M6 onto the Drop tube① .

⚠WARNING

Risk of the Navigator M6 dropping

The Navigator M6 can drop and cause severe injury if the fixing elements have not been properly tightened:

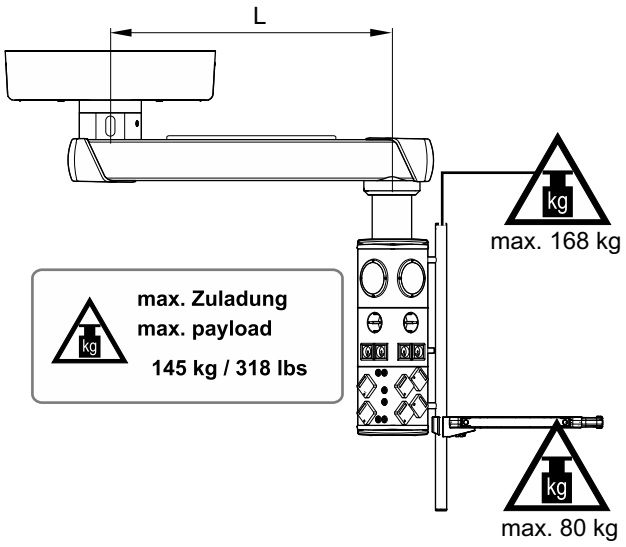
- Using a torque spanner, tighten the 4 Allen cylinder screws M8 – 8.8 or M10 – 8.8② :
- M8 to 23Nm
- M10 to 46Nm

4. Check that the Navigator M6 is securely in place on the pendant system:

- The flange on the Drop tube① must be level with the Navigator M6.
- The 4 Allen cylinder screws M8 – 8.8 or M10 – 8.8② must be tightened to the corresponding torque.

5. Remove the package from the Navigator M6 and dispose of it in compliance with statutory requirements.

Figure 11: What is the maximum loading capacity (payload)?



7.1 What is the maximum loading capacity (payload)?

(See "Figure 11")

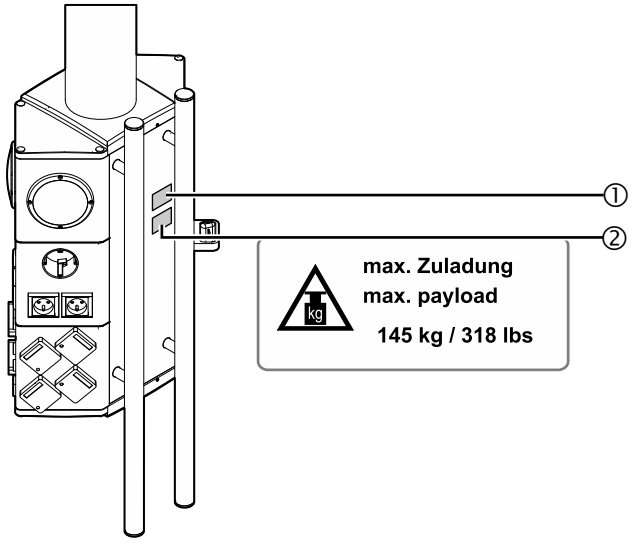
The maximum loading capacity (payload) corresponds to the total weight of all end devices, accessories, etc. which you have fixedly attached or placed onto the Navigator M6 (e.g.: operating shelf, shelf, flat screen, infusions, etc.). A sample calculation is available in Chapter 7.3 on Page 25.

The maximum permissible load bearing capacity on the extension arm differs for the various extension arm lengths "L" of the pendant system. This is why the maximum loading capacity (payload) indicated on the Navigator M6 is specifically adapted to the pendant system to which the Navigator M6 is installed.
In this example, the maximum loading capacity (payload) is 145kg / 318lbs.

The maximum loading capacity (payload) indicated on the Navigator M6 includes the dead weight of the basic equipment (e.g. Drop tube, Navigator M6 and pre-assembled Multi-Function Rack (MFR), the operator handle and the standard rail).

Independently of the maximum loading capacity (payload) indicated on the label, optional accessories may only be loaded with the maximum weight specified in Chapter 18, “Optional Accessories”, on Page 44.

Figure 12: Reading and checking the maximum loading capacity (payload)



7.2 Reading the maximum loading capacity (payload)

(See "Figure 12")

The label ② indicating the maximum loading capacity is attached below the rating plate ① on the Navigator M6.

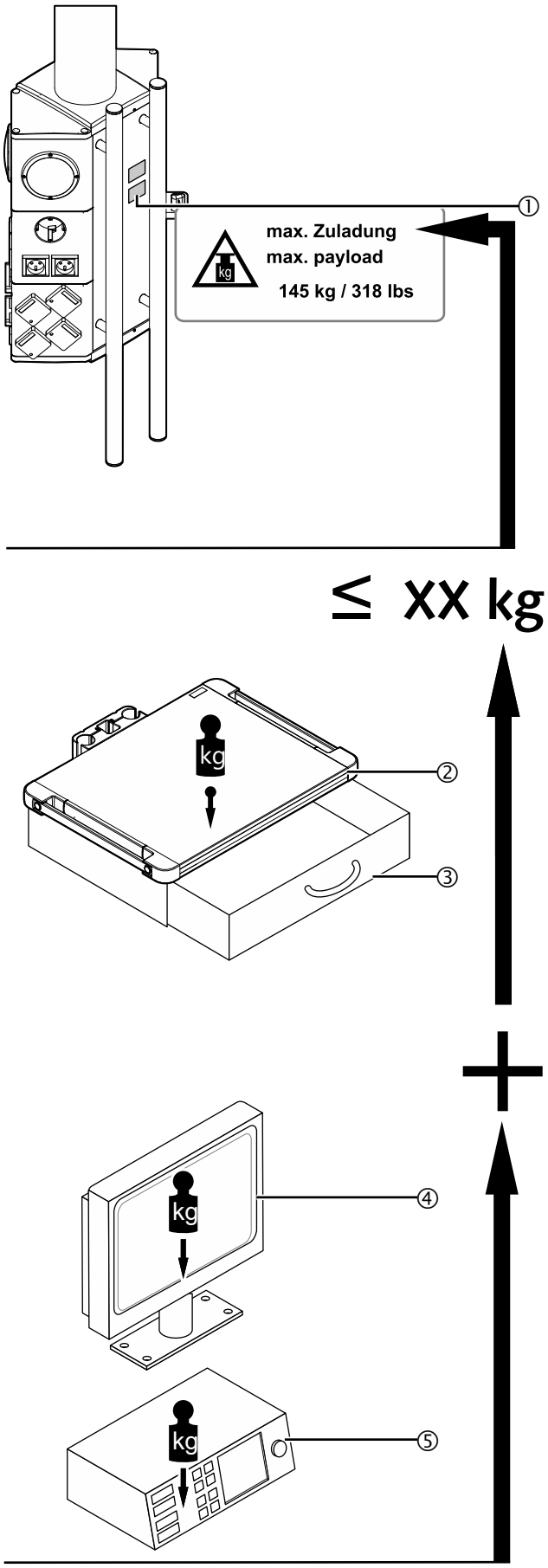
⚠WARNING

The pendant system and the Navigator M6 can drop if the maximum loading capacity (payload) is exceeded

If the maximum permissible loading capacity (payload) has been exceeded, there is a risk that the pendant system, the Navigator M6 or components of the pendant system may disengage from the fastening device and drop:

- The total weight of the fixedly attached or placed end devices, accessories, etc. must not exceed the maximum permissible loading capacity (payload) indicated on the label ② .
- If additional accessories are installed, such as a shelf, the dead weight of the shelf (see Chapter 18, “Optional Accessories”, on Page 44) must be subtracted from the maximum loading capacity (payload).
- Check the maximum loading capacity (payload) specified in Chapter 7.3 on Page 25.

Figure 13: Checking the maximum loading capacity (payload)



7.3 Checking the maximum loading capacity (payload)

(See "Figure 13")

The Figure shows the example of the Navigator M6 with a pre-assembled Multi-Function Rack (MFR).
The label ① indicates a maximum loading capacity (payload) of 145kg for this configuration. If additional accessory components are mounted, their weight must not exceed the weight indicated on the label ① . Check this by means of the following sample calculation:

1. Add the weight of all the accessories (e.g. shelf) and end devices (e.g. flat screen, etc.), other accessory components, etc. installed by you.
- The dead weight of the optional accessories is indicated in Chapter 18, “Optional Accessories”, on Page 44.
2. Compare the sums of the weights with the maximum loading capacity (payload) indicated on the label ① .
? The total weight of the fixedly attached or placed end devices, accessories, etc. must not exceed the maximum permissible loading capacity (payload) indicated on the label ① .

7.3.1 Configuration example

(See "Figure 13")

- For this example the maximum loading capacity (payload) indicated on the label ① is 145kg / 318lbs.
- Dead weight of the additional standard shelf, 520mm large, with standard rail and drawer ② = 9.5kg
- Dead weight of the drawer, Single ③ = 10.9kg
- Dead weight of the flat screen ④ = 12.5kg
- Dead weight of the medical device ⑤ = 34.5kg

7.3.2 Calculation of the maximum loading capacity

(See "Figure 13")

- Maximum loading capacity (payload) = 145kg – (9.5kg + 10.9kg + 12.5kg + 34.5kg) = 77.6kg (residual loading capacity)

7.3.3 Evaluation

- The maximum loading capacity (payload) indicated on the Navigator M6 is 145kg.
- The calculated weight of the additionally installed components is 67.4kg.
- The maximum loading capacity (payload) of 145kg is observed.

7.3.4 Observing the maximum loading capacity (payload) of individual components

- Independently of the maximum loading capacity (payload) indicated on the label, optional accessories may only be loaded with the maximum weight specified in Chapter 18, “Optional Accessories”, on Page 44.

Figure 14: Components described in this chapter

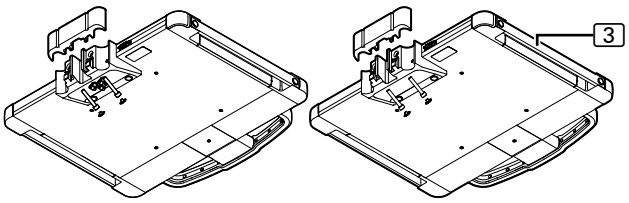


Figure 15: Dismantling the holding clamp from the shelf

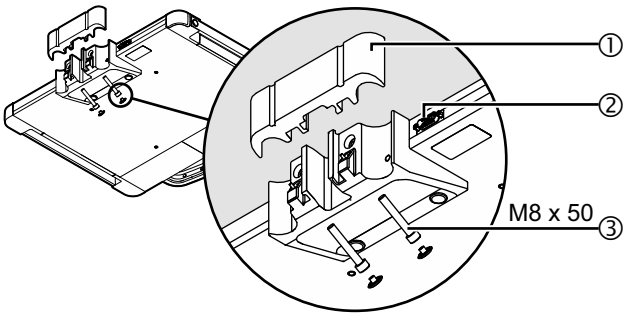
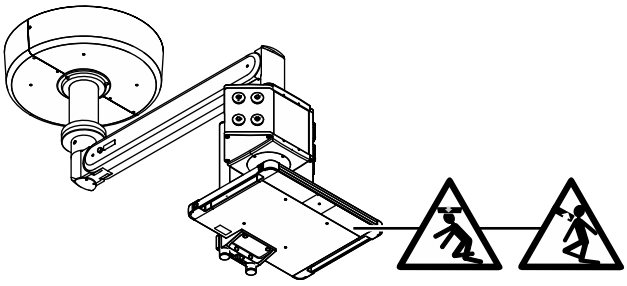
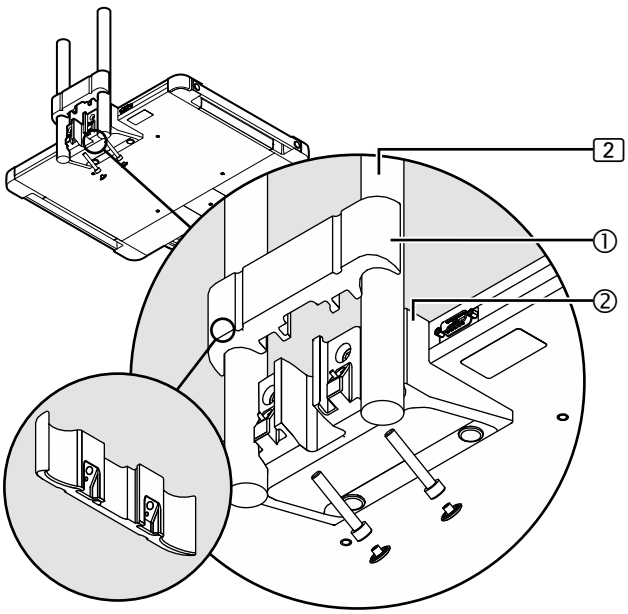


Figure 16: Positioning the shelf

SpacePort





8.1 Components described in this chapter

(See "Figure 14")

The operating shelf [3] illustrated in the Figure is mounted onto the optional Multi-Function Rack (MFR). The steps required for the installation of the operating shelf and the standard shelf are identical.

8.2 Installing the shelf

8.2.1 Dismantling the holding clamp from the shelf

(See "Figure 15")

The Figure shows the operating shelf with D-SUB multi-pin connector ②.

1. Unscrew the 2 Allen cylinder screws M8 x 50 mm – 8.8 – DIN 912 ③ from the bottom of the shelf and keep them in a safe place.
2. Route the holding clamp ① out of the shelf towards the top.

8.2.2 Positioning the shelf

(See "Figure 16")

⚠ WARNING

Only for the Navigator M6 on the pendant system SpacePort®

Sudden release of the end device on the shelf and sudden release of the spring arm

If the optional shelf on the pendant system SpacePort® is not mounted under the Navigator M6 (see Figure), the spring arm joint can break and an end device can drop from the shelf. In this case, the spring arm suddenly jumps up and can cause severe injury:

- Make sure you mount the shelf on the pendant system SpacePort® under the Navigator M6 as illustrated in the Figure.

1. Place the holding clamp ① and then the shelf on the Multi-Function Rack (MFR) [2] as illustrated in the Figure.

• To do this, position the holding clamp ① above the shelf.

2. Push the holding clamp ① onto the shelf fixing device ② from above until the holding clamp ① is flush with the shelf fixing device ②.

• The shelf now sits independently on the Multi-Function Rack (MFR) [2].

⚠ CAUTION

Risk of the shelf dropping

Before being screwed on tightly, the shelf must be monitored and must not be loaded:

- Tighten the screws on the shelf immediately afterwards as described in Chapter 8.2.3 on Page 27.

Figure 17: Tightening the screws on the shelf

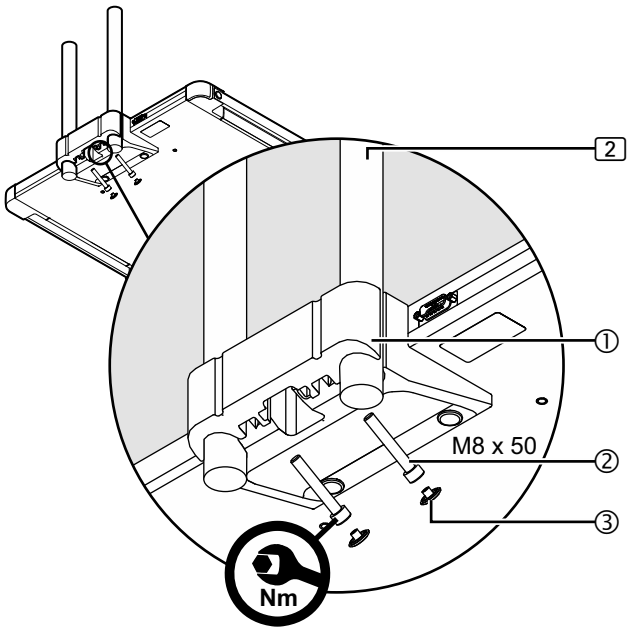


Figure 18: Connecting the cables of the electromagnetic brakes to the operating shelf

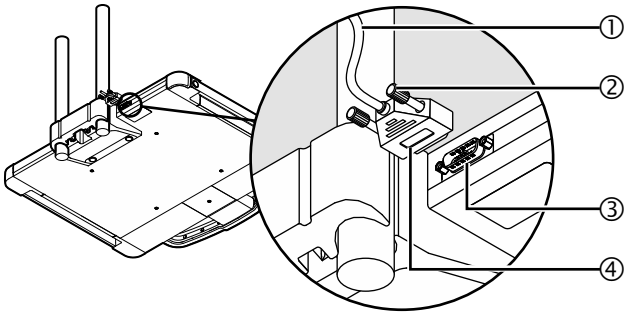
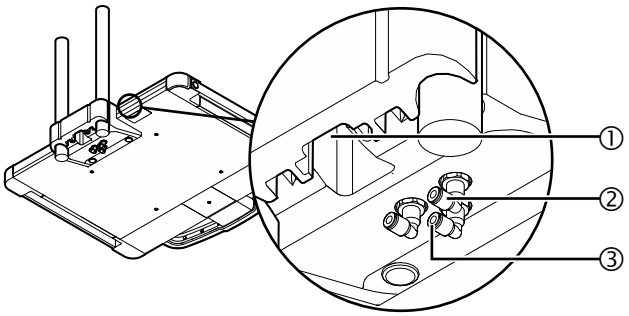


Figure 19: Connecting the pneumatic brake pipes to the operating shelf



8.2.3 Tightening the screws on the shelf

(See "Figure 17")

1. Slightly screw on the holding clamp ① from the bottom of the shelf using 2 Allen cylinder screws M8 x 50 mm ② – 8.8 – DIN 912.
- Position the shelf on the Multi-Function Rack (MFR) [2].
- Be aware that the operating shelf must be mounted as closely as possible to the cable outlet on the Navigator M6.

⚠ WARNING

Risk of the shelf dropping

The shelf can drop if the fastening elements are not tightened properly:

- Tighten the 2 Allen cylinder screws M8 x 50 mm ② to 20 Nm.

2. Check that the shelf is securely in place:
- The shelf must be mounted horizontally to the Multi-Function Rack (MFR) [2].
- The 2 Allen cylinder screws M8 x 50 mm ② must be tightened to 20 Nm.
3. Take 2 protective caps ③ out of the package and place then onto the Allen cylinder screws M8 x 50 mm ②.

8.2.4 Connecting the cables of the electromagnetic brakes to the operating shelf

(See "Figure 18")

1. Position the D-SUB plug connector ④, keeping it straightly aligned, and plug it into the D-SUB multi-pin connector ③ on the rear of the operating shelf.
2. Screw in and tighten the 2 securing screws ②.
- Mount the operating shelf as closely as possible to the cable outlet on the Navigator M6.
3. Push the cable ① back into the cable outlet on the Navigator M6.

8.2.5 Connecting the pneumatic brake pipes to the operating shelf

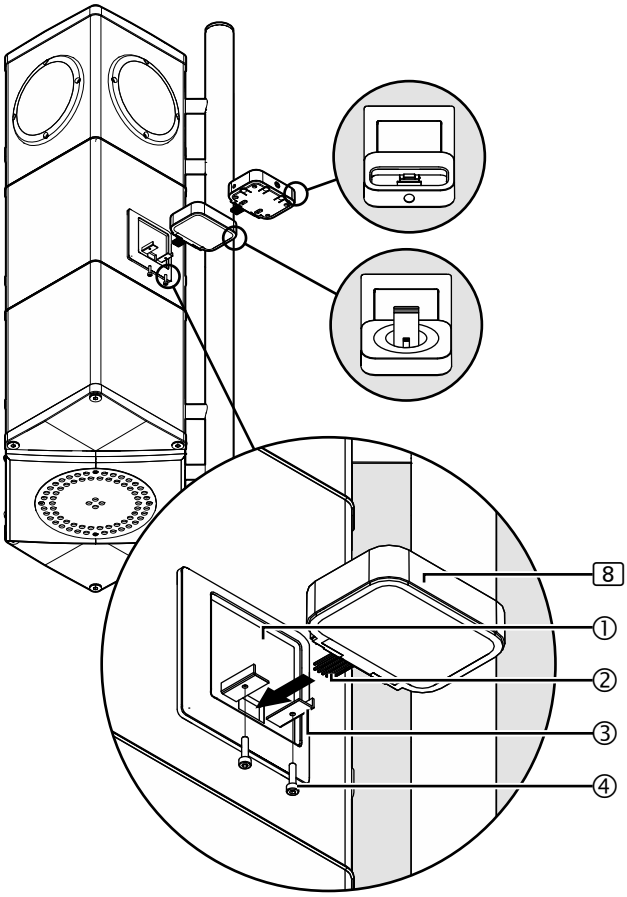
(See "Figure 19")

1. Route the pneumatic brake pipes (not illustrated) through the opening ① towards the brake connecting points ② and plug them in according to the colour marking.
2. Push the pneumatic brake pipes back into the outlet on the Navigator M6.

NOTE – Installing and disengaging brake pipes

The pneumatic supply pipe must be pressureless:
- To install the brake pipes, push them into the brake connecting point ②. If the brake pipe is correctly positioned, it can no longer be withdrawn from the brake connecting point ②.
- To disengage the brake pipes from the brake connecting point ②, push in the unlocking mechanism ③ and then remove the brake pipes.

Figure 20: Mounting the docking station for external digital media players



9.1 Mounting the docking station for external digital media players

(See "Figure 20")

The docking station [8] is available in 2 versions:
1. MediSound-System Bluetooth
2. MediSound-System Interface

The installation steps are identical for both versions.

The sound system consists of the docking station [8] for external digital media players such as MP3 players, smartphones, Apple iPhones or Apple iPods, 4 loudspeakers in the Navigator M6 or 1 spherical ceiling loudspeaker (not illustrated).

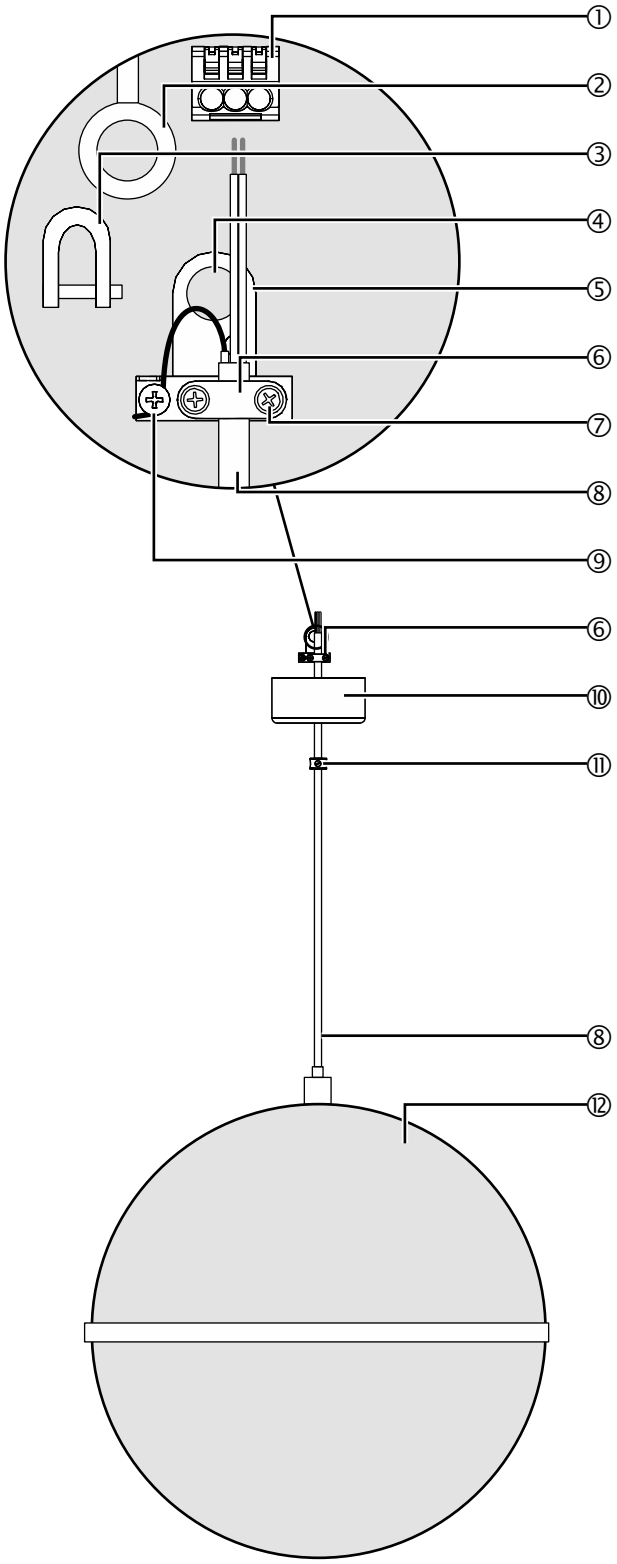
The docking station [8] is mounted onto the mechanism ① on the Navigator M6 prepared for this purpose.

NOTE – Operating the sound system

For detailed information on how to operate the sound system refer to the Operating Instructions of the Navigator M6.

1. Place the docking station [8] straight onto the 2 holders ③ and gently push the plug pins ② into the mounting aperture (see arrow) on the prepared mechanism ①.
- Make sure that the plug pins ② are not twisted or damaged.
2. Screw in and tighten 2 metal screws M3 x 12 mm ④ as illustrated in the Figure.
3. Check that the docking station [8] is securely in place:
- The docking station [8] must be level with the Navigator M6 [1].
- The 2 metal screws M3 x 12 mm ④ must be tightened.

Figure 21: Mounting the ceiling loudspeaker



9.2 Mounting the ceiling loudspeaker

(See "Figure 21")

The ceiling loudspeaker⑬ weighs approx. 4.5kg. Due to the different ceiling structures at the place of installation, no binding Installation Instructions can be provided.

⚠WARNING

Ceiling loudspeaker falling

A falling loudspeaker may cause serious injury:

- The person in charge of the installation is responsible for selecting the correct fastening elements depending on the requirements for the ceiling type at the installation site and in accordance with the rules for safe installation.

NOTE – Connecting the audio cables

- The audio cable of the Navigator M6 is 10 metres long. It must be routed from the Navigator M6 through the pendant system to the ceiling loudspeaker.
- Do not attach the ceiling loudspeaker too far away from the Navigator M6. Shorten any excess cable lengths or stow them in the canopy⑩.

1. Route the audio cable⑧ (approx. 2.5 m long) of the ceiling loudspeaker⑫ through the adjusting collar⑪, the canopy⑩ and the cable holder⑥ of the cord grip⑤.
2. Strip the insulation from the audio cable⑧.
3. Connect the pink and grey cables to the WAGO terminal① of the audio cable on the Navigator M6.

- Connect the pink cable to "4 Ohm" and the grey cable to "0".

4. Wind the steel cable (beige) around the cylinder head screw M3 x 5 mm⑨ and screw in the cylinder head screw M3 x 5 mm⑨.
5. Screw tight the 2 fillister head screws M3 x 12mm⑦ of the cable holder⑥.
6. Check that the audio cable⑧ is securely in place:

- Using the cylinder head screw M3 x 5 mm⑨, the steel cable must be secured against withdrawal.
- The audio cable⑧ must be securely held by the cable holder⑥ of the cord grip⑤.

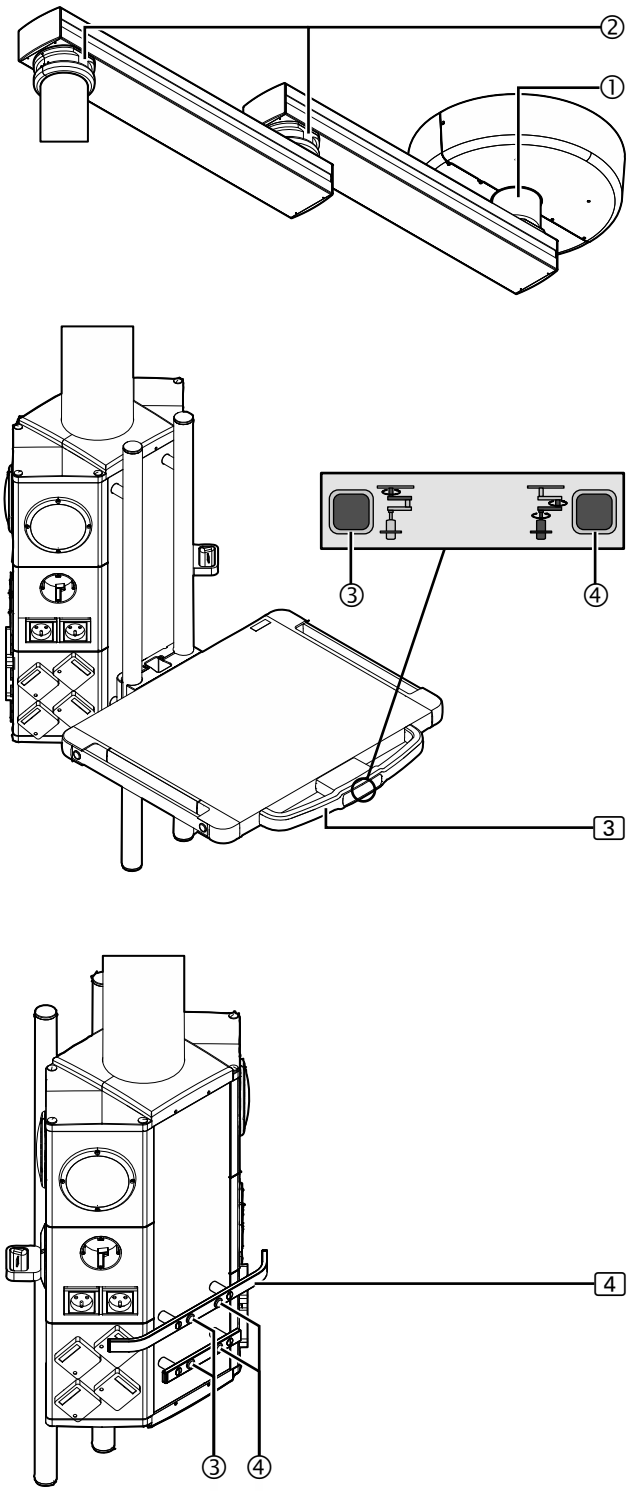
7. Anchor 1 eyebolt② (not included in the scope of delivery) for ceiling mounting at a suitable position in the ceiling in accordance with the fastening element manufacturer's instructions.
8. Route a shackle③ (not included in the scope of delivery) through the fixing opening④ of the cord grip⑤ . Next, hook the shackle③ into the eyebolt② and then secure it.

- The shackle③ must be screwed or secured with a pin in order to ensure that it does not open even under load.

9. Push the canopy⑩ up to the ceiling and attach it at the correct height using the adjusting collar⑪.
10. Screw tight the adjusting collar⑪ on the connecting cable⑧.

- Do not screw the adjusting collar⑪ on the connecting cable⑧ too tight so as not to damage the connecting cable⑧.

Figure 22: Marking the braking points on the pendant system



(See "Figure 22")

The braking points must be marked on the pendant systems OndaScope® 400 / OndaScope® 600 and Multi-Movement Pendant MMP 90 / MMP 200. The Figure shows the example of the pendant system OndaScope® 400.

The optional brake buttons ③/④ are located on the operating shelf [3], the standard rail [4] or directly on the Navigator M6. To release and tighten the pneumatic brakes on the pendant system, press the corresponding brake button ③/④.

The brake buttons ③/④ are colour coded and assigned to a bearing/rotating point ①/② each:

- Left-hand green brake button ④ for the upper bearing/rotating point ①.
- Right-hand blue brake button ③ for the lower bearing/rotating point ② and the Navigator M6.

1. Take the 2 coloured labels out of the accessories provided.
2. In accordance with the assignment to the brake buttons ③/④ stick the labels onto the bearing/rotating points ①/② and make sure that they are clearly visible:
   - Stick the green label onto the upper bearing/rotating point ①.
   - Stick the blue label onto the lower bearing/rotating point ②.
3. Check that the labels are clearly visible from the Navigator M6.

11.1 Electrical safety test

For start-up following installation, proper initial commissioning of the entire pendant system with the Navigator M6 must be carried out e.g. based on the test standard for medical electrical equipment EN 62353.

11.2 Gas inspection

1. Gas outlets and marking in accordance with DIN EN ISO 9170-1 or DIN EN ISO 9170-2
2. Leakage in accordance with DIN EN ISO 11197
3. Congestion in accordance with DIN EN ISO 7396-1 or DIN EN ISO 7396-2
4. Solid contamination in accordance with DIN EN ISO 7396-1 or DIN EN ISO 7396-2
5. Gas type in accordance with DIN EN ISO 7396-1 or DIN EN ISO 7396-2

11.3 Mechanical collision test

1. When swivelling the Navigator M6 and adjusting its height, make sure that no collisions can occur with:

- other pendant systems,
- ceilings or walls,
- other assembly units.

Initial commissioning

1. The Navigator M6 must be properly installed. Instructions for installation are included in the scope of delivery of the product.
2. For start-up following installation, proper initial commissioning must be carried out for the entire pendant system and the Navigator M6.

Functional test

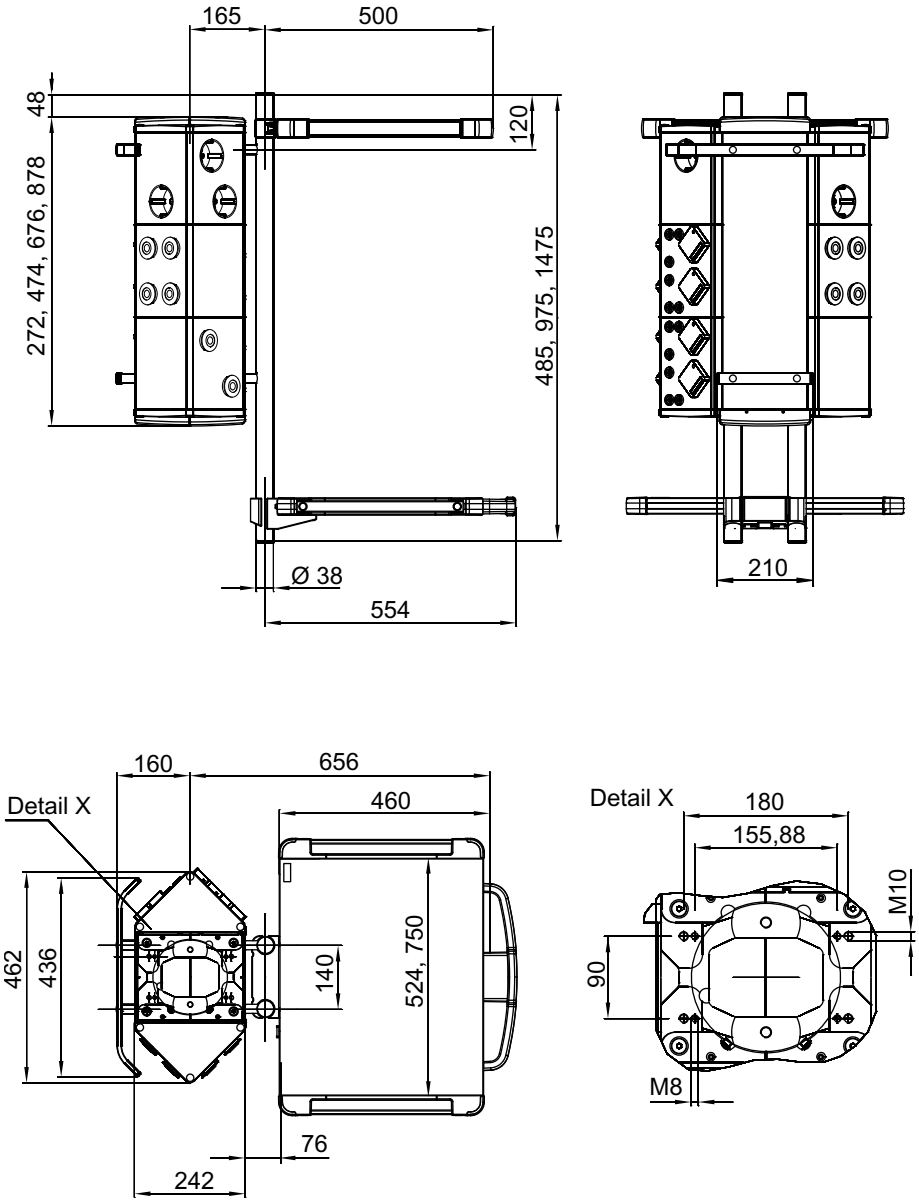
Prior to using the pendant system and the Navigator M6 on a patient for the first time, a functional test must be performed at the installation site. This functional test must be carried out by the operator or a person authorised by the operator, and the persons authorised by the operator must be duly instructed.
This requirement is considered fulfilled if:

1. The functional reliability of the pendant system and the Navigator M6 has been ensured.
2. The maximum permissible loading capacity (payload) has been safely determined and is indicated on a label attached to the Navigator M6.
3. The proper functioning of the device has been approved by the operator during initial commissioning and documented by signing a test report in accordance with Appendix G DIN EN 62353.

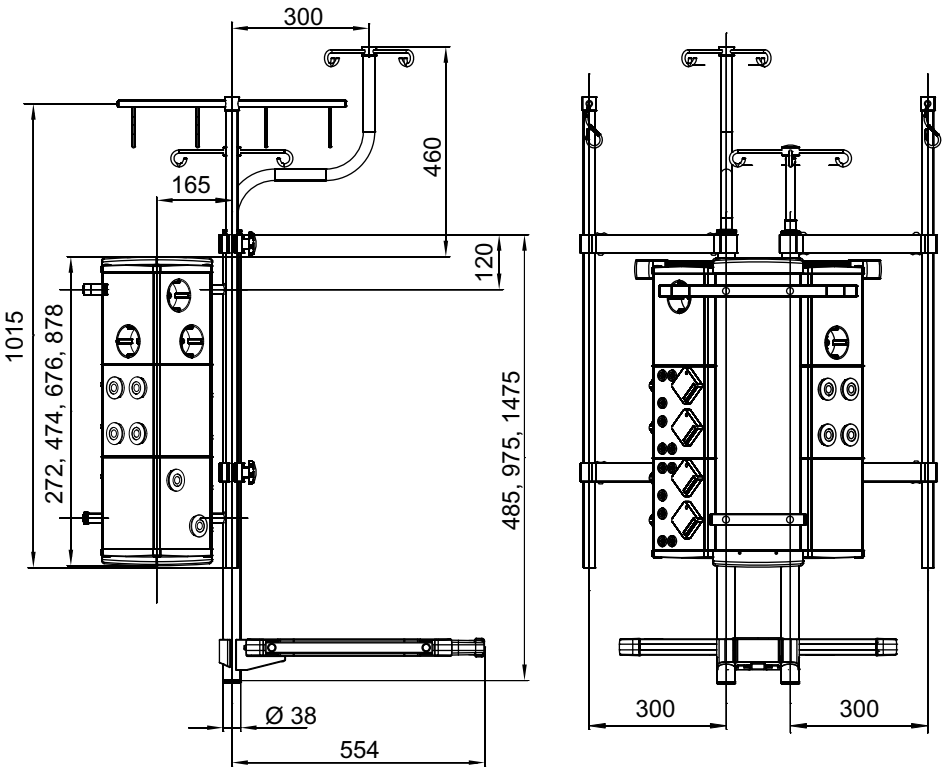
The following points must be observed during handover to the operator:

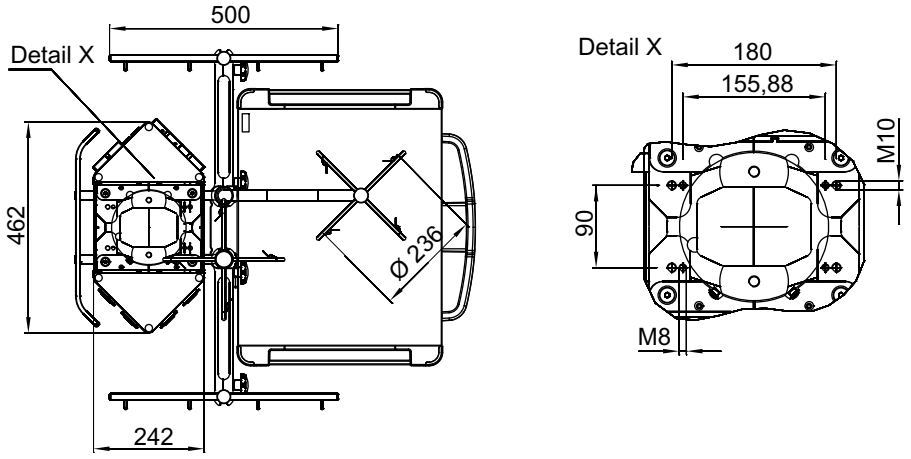
1. The pendant system and the Navigator M6 must not be handed over to the operator until they have been tested.
2. Handover must be documented in writing including confirmation by the operator.
3. On handover, the operator must be instructed in the functioning and effect of the maximum loading capacity (payload).
4. In addition, the operator must be instructed in the functioning, operation, cleaning and disinfection of the pendant system and the Navigator M6.
5. Furthermore, on handover, the operator must be instructed in the adjustments permitted according to the Operating Instructions included in the scope of delivery.
6. On completion of the instruction, an instruction certificate must be created and signed in order to document that the operator/user has understood the special operator control actions required for normal use.

13.1 Navigator M6 with Multi-Function Rack (MFR)



13.2 Navigator M6 with infusion accessories





Modes of operation	The Navigator M6 is suitable for continuous operation.
Duty cycle of the height adjustment mechanism (only pendant systems MMP 90 / MMP 200 and Navigator Lift ™ 150 / Navigator Lift ™ 250)	• The maximum duty cycle of the height adjustment mechanism on the motor arm (only pendant systems MMP 90 / MMP 200 and Navigator Lift ™ 150 / Navigator Lift ™ 250) must not exceed 3 minutes: – If the height adjustment mechanism is actuated over a longer period of time, the electric motor of the motor arm may switch off automatically as a protection measure against overheating. – In order to prevent an overload of the electric motor, make sure you wait at least 30 minutes after actuating the height adjustment mechanism before putting it into operation. Afterwards the height adjustment mechanism can be operated once again for 3 minutes.
Duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes)	• The maximum duty cycle of the electromagnetic brakes (only for pendant systems with electromagnetic brakes) must not exceed 1 minute: – If the electromagnetic brakes are actuated over a longer period of time, the power pack may switch off automatically as a protection measure against overheating. – Once the power pack has switched off, it must cool down for 10 minutes and then be disconnected from the mains for 10 seconds before being switched back on again. Normal system operation may only be resumed afterwards. To prevent safety cut-offs, the maximum duty cycle should not be exceeded.
Duty cycle of pneumatic brakes	The pneumatic brakes are suitable for continuous operation.
Rating plate	The rating plate and further labels are attached to the Navigator M6 (see Chapter 5 on Page 18.
Maximum loading capacity (payload) on the Navigator M6	The Navigator M6 is suitable and approved for the maximum loading capacity (payload) specified in Chapter 7 on Page 24. If you cannot clearly determine the maximum loading capacity (payload) as specified in Chapter 7 on Page 24, contact Nuvo in order to prevent damage to persons or property.
Dead weight of the pre-assembled components*	Sound system ..... pre-assembled* Lighting system ..... pre-assembled* Standard rail ..... pre-assembled* Optional Multi-Function Rack (MFR) ..... pre-assembled* * The maximum loading capacity (payload) of the Navigator M6 already includes the maximum loading capacity (payload) of the pre-assembled components.
Maximum loading capacity (payload) of the components	Optional standard rail ..... up to 10 kg Optional Multi-Function Rack (MFR) ..... up to 168 kg* * If required, the maximum loading capacity (payload) in accordance with the calculation in Chapter 7 on Page 24 must be reduced accordingly.
Electrical data	Rated voltage ..... 120 / 230 V Rated frequency ..... 60 / 50 Hz Rated current ..... up to 20 / 16 A per electric circuit Maximum number of electric circuits ..... up to 4 electric circuits with 4 sockets each

Gas supply data (gas outlet points in accordance with DIN 13260-2)	Depending on the customer-specific equipment Medical gases ..... in accordance with DIN EN ISO 9170-1 Compressed air ..... 5 bar Compressed air outlet, air motor ..... 10 bar Vacuum ..... 5 bar Anaesthetic gas suction ..... in accordance with DIN EN ISO 9170-2 Depending on the customer-specific equipment
Sound system data	Supply voltage ..... 12 V / DC Output power ..... 1.2 W Loudspeaker impedance ..... 8 Ohm Frequency response ..... 30 Hz ~ 20 KHz – 3 dB Output voltage lineout ..... 0.2 V / AC (depending on the mobile device) Signal-to-interference ratio, loudspeakers ..... 70 dB IR sensor frequency ..... 38 KHz
Protection class / type	Protection class in accordance with EN 60601-1 ..... I IP classification in accordance with IEC 60529 ..... IP 20
Noise level	Sound energy level ..... 65 db(A) (EN ISO 3746) not exceeded
Operation	Manual forces ..... < 100 N
Medical Device Directive 93/42/EEC	Classification ..... IIb
Applicable standards, laws and directives	• Medical Devices Act (MPG) • MDD 93/42/EEC – Medical Device Directive (MDD) • EN 60601-1 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance • DIN EN ISO 11197 – Medical Supply Units
Approvals of the standard equipment	• Recognised NRTL component

Models

- Navigator M6 on the Nuvo pendant system.

Approved adaptions

The following Nuvo products are approved as adaptions to the Navigator M6:

- Chapter 16, “Approved Nuvo Products”, on Page 43,
- Chapter 17, “Approved Third-Party Products”, on Page 43:
  - The components have been adapted to each other and are safe to operate. Any other type of installation, and in particular the use of components from third-party manufacturers, is strictly prohibited because these components can be potential sources of danger.
  - The combination of any other Nuvo product with the Navigator M6 must be approved by Nuvo Surgical. If applicable, the conformity assessment must be repeated.

Read the Installation Instructions for combined products

- The Navigator M6 is combined with products of other manufacturers as described in Chapter 17, “Approved Third-Party Products”, on Page 43.
  To prevent dangerous overload, which can damage or lead to a collapse of the pendant system and the Navigator M6, the maximum loading capacities specified must be adhered to.
  - The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.
  - Read the Operating Instructions provided by the third-party manufacturer to obtain the information required for the operation of the end device.
- Power packs intended for the supply of end devices must ensure electrical isolation and provide two protective measures in accordance with IEC 60601-1.

15.1 Guidelines and manufacturer's declarations

15.1.1 Electromagnetic emissions

The Navigator M6 is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of the Navigator M6 must ensure that it is used in such an environment.

Emission tests	Compliance	ELECTROMAGNETIC ENVIRONMENT – Guideline
RF emissions in accordance with CISPR 11	Group 1	The Navigator M6 uses RF energy only for its internal FUNCTIONING. Therefore, its RF emissions are very low and are not likely to cause any interference with electronic equipment nearby.
RF emissions in accordance with CISPR 11	Class A	The Navigator M6 is suitable for operation in professional healthcare facilities.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions in accordance with IEC 61000-3-3	Complies	

15.1.2 Electromagnetic immunity

The Navigator M6 is intended for use in the ELECTROMAGNETIC environment specified below. The customer or the user of the Navigator M6 should ensure that it is used in such an environment.

Interference immunity test	Test level in accordance with IEC 60601	Test result
Electrostatic discharge in accordance with IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	passed
Electrical fast transients / bursts in accordance with IEC 61000-4-4	±2kV 100kHz repetition rate	passed
Surges Line-to-line in accordance with IEC 61000-4-5	±0.5kV, ±1kV	passed
Surges Line-to-earth in accordance with IEC 61000-4-5	±0.5kV, ±1kV, ±2kV	passed
Voltage dips in accordance with IEC 61000-4-11	0% U_T; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	passed
	0% U_T; 1 period and 70% U_T; 25/30 periods Single phase: at 0 degrees	passed
Voltage interruptions in accordance with IEC 61000-4-11	0% U_T; 250/300 periods	passed
Power frequency magnetic field immunity in accordance with IEC 61000-4-8	30A/m 50Hz or 60Hz	passed

Please note:
U_T is the a.c. mains voltage prior to application of the test level.

Cont.

The Navigator M6 is intended for use in the ELECTROMAGNETIC environment specified below. The customer or the user of the Navigator M6 should ensure that it is used in such an environment.

Interference immunity test	Test level in accordance with IEC 60601	Compliance level
Immunity to conducted disturbances, induced by radiofrequency fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands from 0.15 MHz to 80 MHz 80 % AM at 1 kHz	passed
High-frequency electromagnetic fields in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	passed

NOTE 1
At 80 MHz and 800 MHz, the higher value applies.

NOTE 2
These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The field strength of stationary transmitters, including the base stations of mobile phones and mobile land mobile radios, amateur radio stations, AM and FM radio and TV broadcasting transmitters, cannot be precisely predetermined theoretically. To assess the electromagnetic environment due to stationary RF transmitters, an electromagnetic site survey should be considered. If the field strength measured in the location in which the Navigator M6 is used exceeds the applicable RF compliance level above, the Navigator M6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Navigator M6.

[b] Field strengths over the 150 kHz to 80 MHz frequency range should be less than 3 V/m.

15.1.3 Test specifications

Test specifications for the INTERFERENCE IMMUNITY of ENCLOSURES against high-frequency wireless communication facilities

Test frequency MHz	Frequency band [a] MHz	Radio service [a]	Modulation [b]	Maximum power W	Distance m	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz stroke 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1998	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE
To reach the IMMUNITY TEST LEVELS, the distance between the transmitting antenna and the ME DEVICE or ME SYSTEM can be reduced to 1 m if required. The 1 m test distance is permitted in accordance with IEC 61000-4-3.

[a] For certain radio services only the frequencies for the radio connection from the mobile communication device to the base station ("up-link") are indicated in the table.
[b] The carrier must be modulated with a square wave signal with a 50 % duty cycle.
[c] As an alternative to frequency modulation (FM), pulse modulation with a 50 % duty cycle at 18 Hz can be used because pulse modulation would also represent the worst case (but not the actual modulation).

⚠WARNING

Do not operate this device immediately next to or together with other devices stacked on top of each other because this could result in improper operation. If operation in the described manner is unavoidable, this device and all other devices should be monitored in order to ensure proper operation."

⚠WARNING

The use of other ACCESSORIES, other converters and other cables than those prescribed or provided by the MANUFACTURER of this device can lead to increased ELECTROMAGNETIC INTERFERENCE EMISSIONS or reduced electromagnetic immunity of the device, and thus improper operation.

⚠WARNING

PORTABLE RF communication devices (radio equipment, including ACCESSORIES such as antenna cables and external antennas) should not be used at a distance of less than 30 cm (12 inches) from the Navigator M6 components and cables specified by the MANUFACTURER. Be aware that the performance of the device can be reduced if this safety rule is not observed.

Products approved for use on the Navigator M6	Maximum load bearing capacity
Nuvo accessories as described in Chapter 18 on Page 44	See Chapter 18 on Page 44

17 Approved Third-Party Products

Third-party end devices with CE mark approved for use on the Multi-Function Rack (MFR).
Flat screens
Infusion accessories

Third-party end devices with CE mark approved for use on the shelf.
HF surgical devices
Endoscopy devices
Respiratory apparatuses
Patient monitors
Flat screens

For more detailed information on how to install additional end devices to the Navigator M6, please contact Nuvo customer service so as to prevent damage to persons or property: Phone: +1 (800) 663-1152 (USA and CANADA) Phone: +1 (814) 899-4220 (INTERNATIONAL)
The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.

Designation	Dead weight	Maximum payload
Filing basket with holder	0.9kg	2kg
Storage tray, stainless steel, 300 x 240 mm	1.0kg	9kg
Hooks for standard rail	0.2kg	3kg
Examination light with flex arm	3.0kg	---
Halogen lamp LUX 50 FX	1.7kg	---
Halogen lamp LUX 50 SX	1.6kg	---
Holding clamp, 25 x 10mm, with 25.3 mm drill hole	0.3kg	6kg
INFU crossbar	0.8kg	10kg
Infusion extension	2.6kg	10kg / 4 x 2kg
Infusion holder with 3 holes and star handle	0.7kg	4kg
Infusion cross, bent	1.8kg	4 x 2kg
Infusion cross, straight	1.8kg	4 x 2kg
Infusion rack	3.0kg	30kg / 4 x 2kg
Catheter basket 480 x 150 x 100 mm	1.0kg	3kg
Catheter basket 280 x 150 x 100 mm	1.0kg	3kg
Refuse bag holder with standard rail claw	0.8kg	5kg
Standard rail claw, 2 counterbores for M5 screw	0.2kg	4kg
Standard rail claw, 4 counterbores for M5 screw	0.3kg	4kg
Rail fastening device	0.3kg	1.8kg
Dual drawer	18.0kg	10kg
Single drawer	10.9 kg	10kg
S-INFU od	1,8kg	4 x 2kg
Operating shelf 500 mm width, without standard rail, with switch with two brake buttons and two up and down buttons	8.3kg	50kg
Operating shelf 500 mm width, with standard rail, with switch with two brake buttons and two up and down buttons	8.9kg	50kg
Operating shelf, 750 mm width, without standard rail, with switch with two brake buttons and two up and down buttons	9.0kg	50kg
Operating shelf, 750 mm width, with standard rail, with switch with two brake buttons and two up and down buttons	9.6 kg	50kg
Standard shelf, 500 mm width, without standard rail	6.9kg	50kg
Standard shelf, 500 mm width, with standard rail	8.1kg	50kg
Standard shelf, 750 mm width, without standard rail	7.6kg	50kg
Standard shelf, 750 mm width, with standard rail	8.8kg	50kg
Operating shelf 2nd gen. 520 mm with 2 brake buttons	8.2kg	80kg
Operating shelf 2nd gen. 750 mm with 2 brake buttons	10.5kg	80kg
Standard shelf 2nd gen. 520 mm without standard rail	7.2kg	80kg
Standard shelf 2nd gen. 520 mm with standard rails	9.5kg	80kg
Standard shelf 2nd gen. 750 mm without standard rail	8.0kg	80kg
Standard shelf 2nd gen. 750 mm with standard rails	10.3kg	80kg
For the specifications of the Haeberle equipment and endoscopy carts refer to our Nuvo Pendant Manager configuration software or contact your partner in our sales department.		
To order accessories please contact our sales team.		

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